US009402726B2

(12) **United States Patent**
Linderman et al.

(10) **Patent No.: US 9,402,726 B2**
(45) **Date of Patent: Aug. 2, 2016**

(54) **REVISION SYSTEMS, TOOLS AND METHODS FOR REVISING JOINT ARTHROPLASTY IMPLANTS**

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(73) Assignee: **ConforMIS, Inc.**, Bedford, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 12 days.

(21) Appl. No.: **14/238,989**

(22) PCT Filed: **Aug. 15, 2012**

(86) PCT No.: **PCT/US2012/050964**

§ 371 (c)(1),
(2), (4) Date: **Apr. 3, 2014**

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PCT Pub. Date: **Feb. 21, 2013**

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Related U.S. Application Data

(60) Provisional application No. 61/523,756, filed on Aug. 15, 2011.

(51) **Int. Cl.**
A61F 2/30 (2006.01)
A61B 17/15 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/30*** (2013.01); ***A61B 17/155*** (2013.01); ***A61B 17/157*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 2/38; A61F 2/28; A61F 2002/2835; A61F 2/3094; A61F 2/30942; A61F 2/30
See application file for complete search history.

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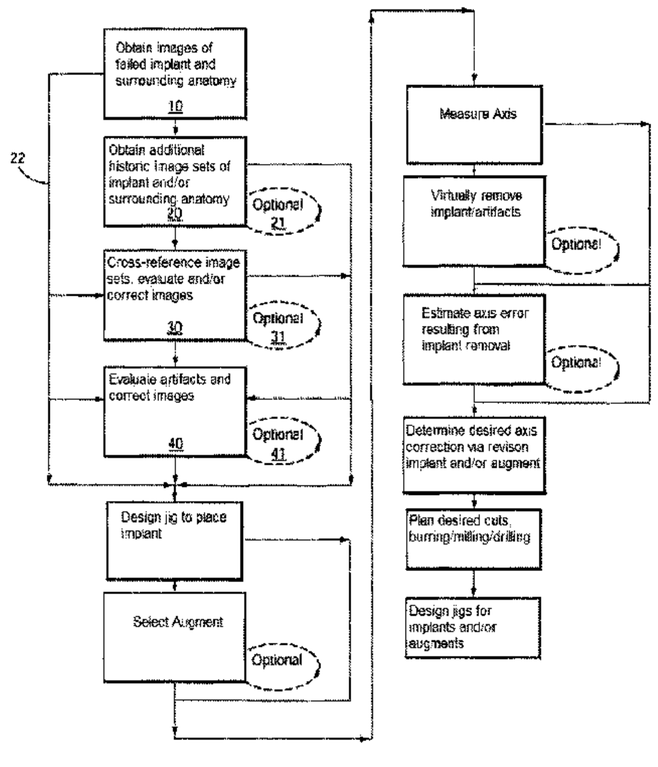
Primary Examiner — Jason-Dennis Stewart
(74) *Attorney, Agent, or Firm* — Sunstein Kann Murphy & Timbers LLP

(57) **ABSTRACT**

Disclosed herein are methods, compositions and tools for repairing an articular joint having a failed implant. The articular repair systems are customizable or highly selectable by or adaptable to individual patients and geared toward providing optimal fit and function. The surgical tools are designed to be customizable or highly selectable by or adaptable to individual patients to increase the speed, accuracy and simplicity of performing total or partial arthroplasty including revision surgeries.

9 Claims, 45 Drawing Sheets



(51) **Int. Cl.**

B23P 15/00	(2006.01)
A61F 2/38	(2006.01)
A61B 17/17	(2006.01)
A61B 17/56	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/158*** (2013.01); ***A61B 17/1746*** (2013.01); ***A61F 2/30756*** (2013.01); ***B23P 15/00*** (2013.01); *A61B 17/1714* (2013.01); *A61B 17/1764* (2013.01); *A61B 2017/568* (2013.01); *A61F 2/38* (2013.01); *A61F 2002/3069* (2013.01); *A61F 2002/3096* (2013.01); *A61F 2002/30963* (2013.01); *Y10T 29/49* (2015.01)

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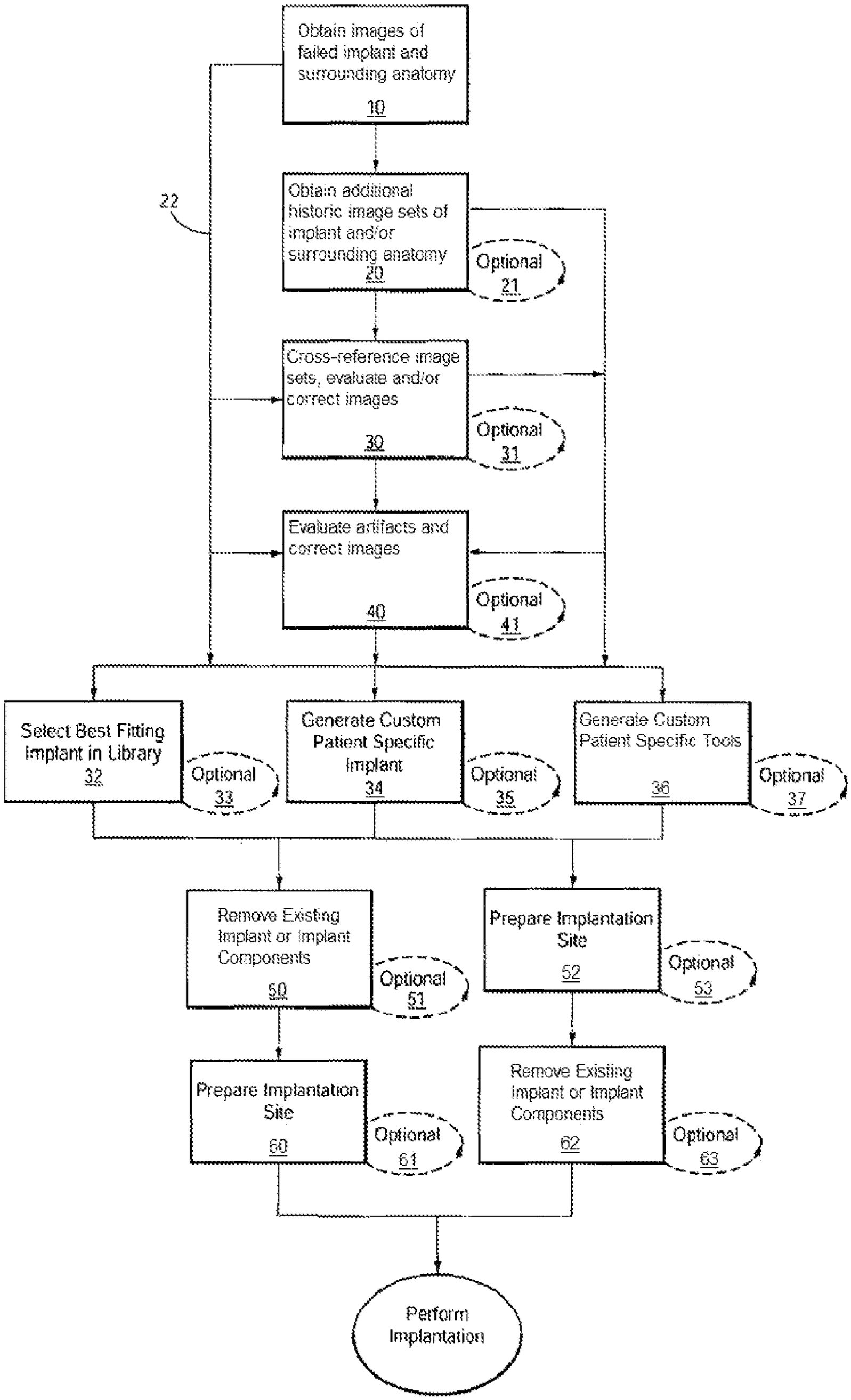
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10
22
Obtain additional historic image sets of implant and/or surrounding anatomy
20
Optional
21
Cross-reference image sets, evaluate and/or correct images
30
Optional
31
Evaluate artifacts and correct images
40
Optional
41
Select Best Fitting Implant in Library
32
Optional
33
Generate Custom Patient Specific Implant
34
Optional
35
Generate Custom Patient Specific Tools
36
Optional
37
Remove Existing Implant or Implant Components
50
Optional
51
Prepare Implantation Site
52
Optional
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Prepare Implantation Site
60
Optional
61
Remove Existing Implant or Implant Components
62
Optional
63
Perform Implantation

FIG. 1A

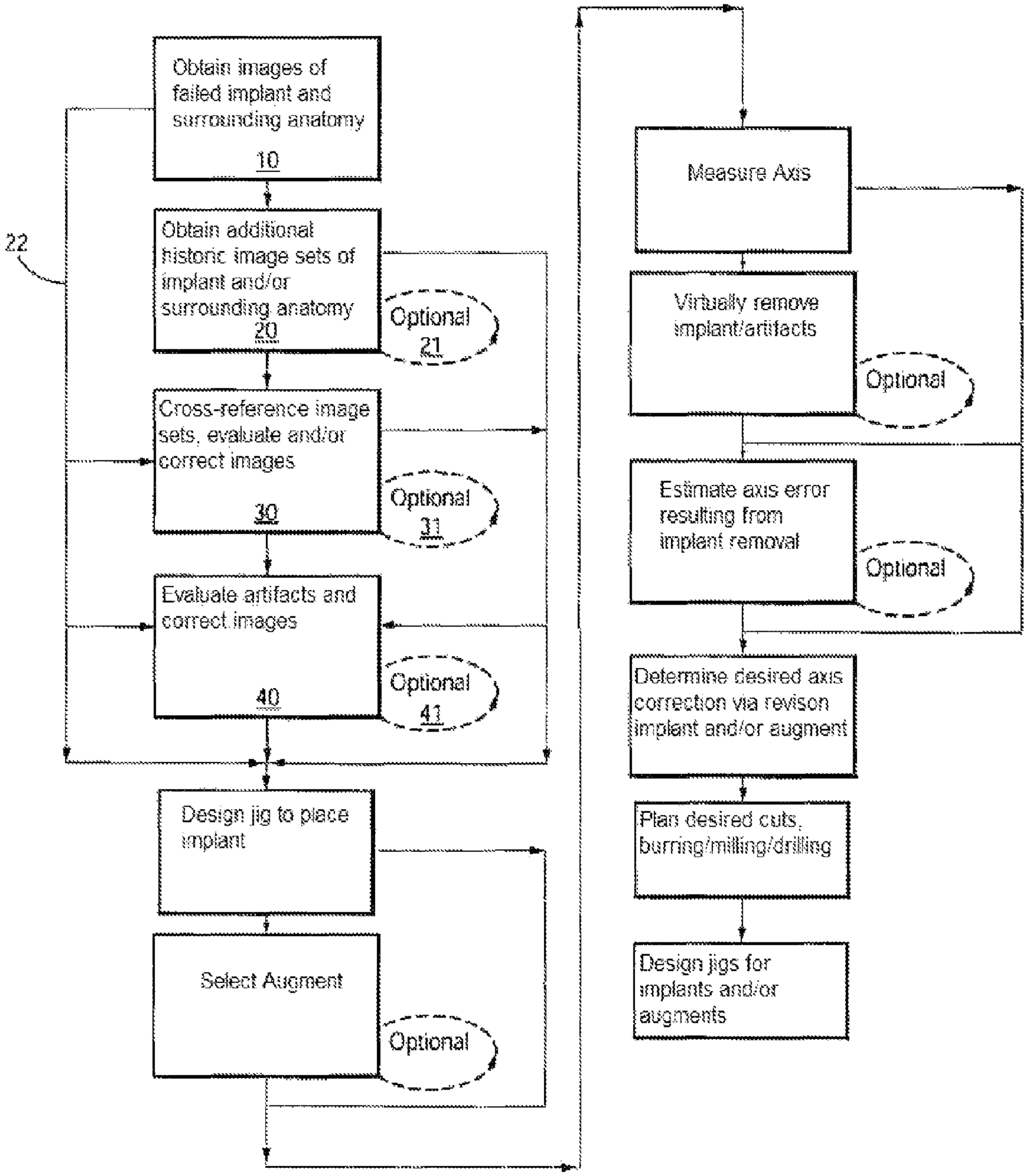

Obtain images of failed implant and surrounding anatomy
10
22
Obtain additional historic image sets of implant and/or surrounding anatomy
20
Optional
21
Cross-reference image sets, evaluate and/or correct images
30
Optional
31
Evaluate artifacts and correct images
40
Optional
41
Design jig to place implant
Select Augment
Optional
Measure Axis
Virtually remove implant/artifacts
Optional
Estimate axis error resulting from implant removal
Optional
Determine desired axis correction via revison implant and/or augment
Plan desired cuts, burning/milling/drilling
Design jigs for implants and/or augments

FIG. 1B

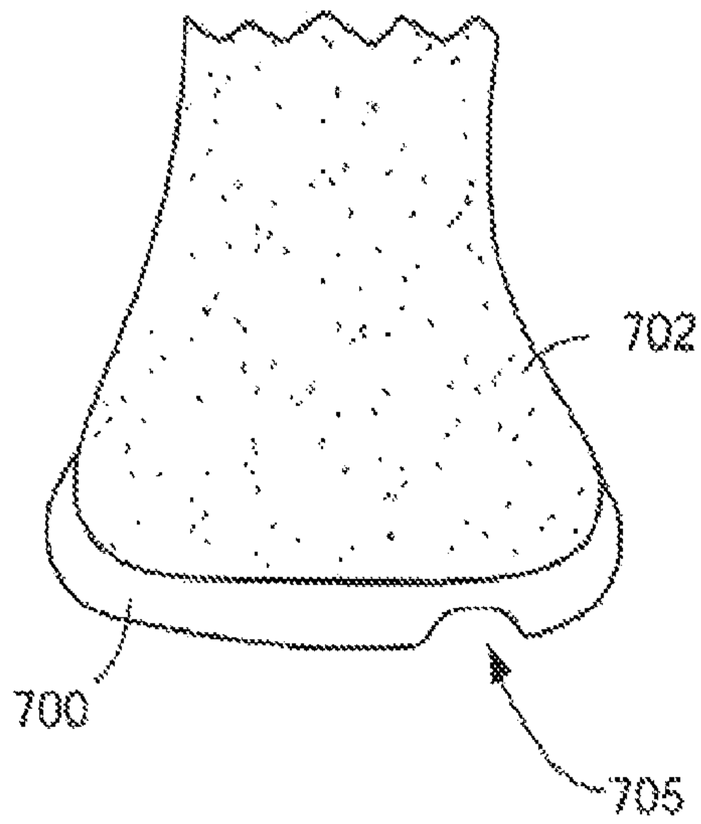


FIG. 2A

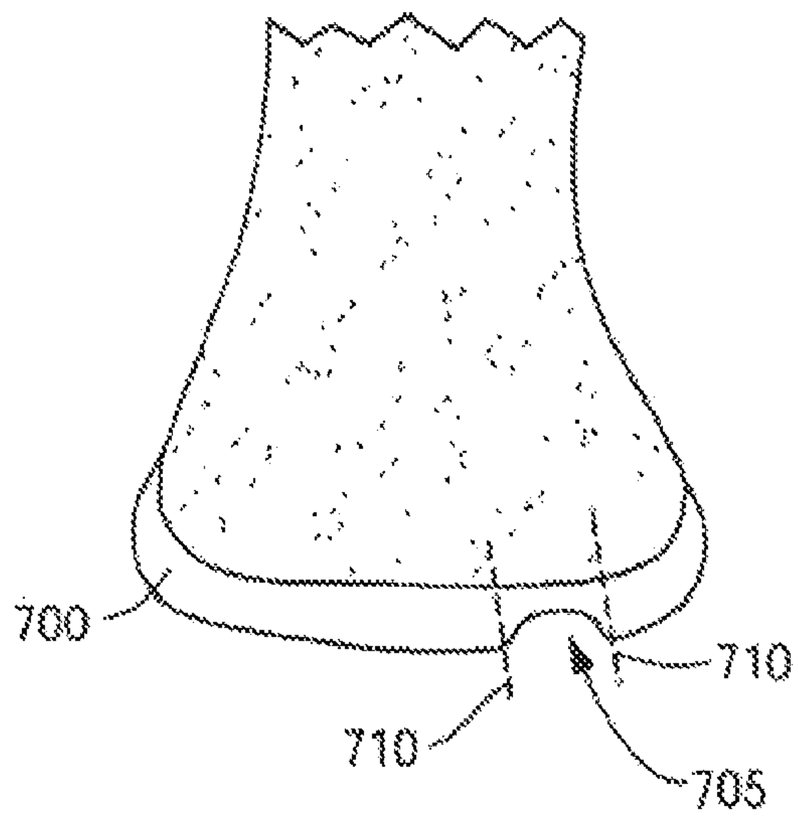


FIG. 2B

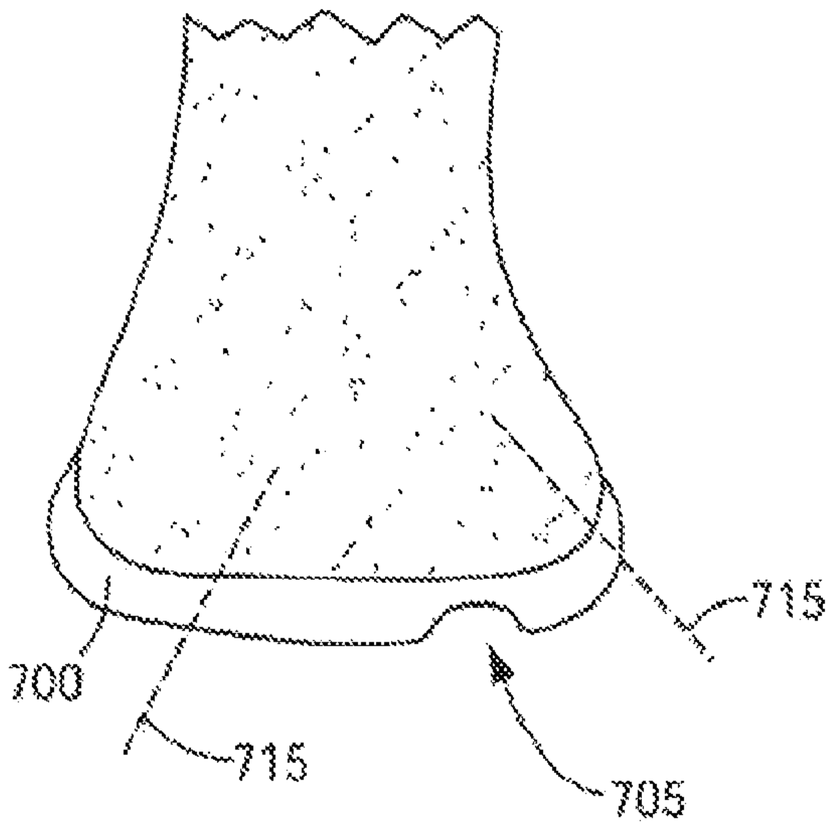


FIG. 2C

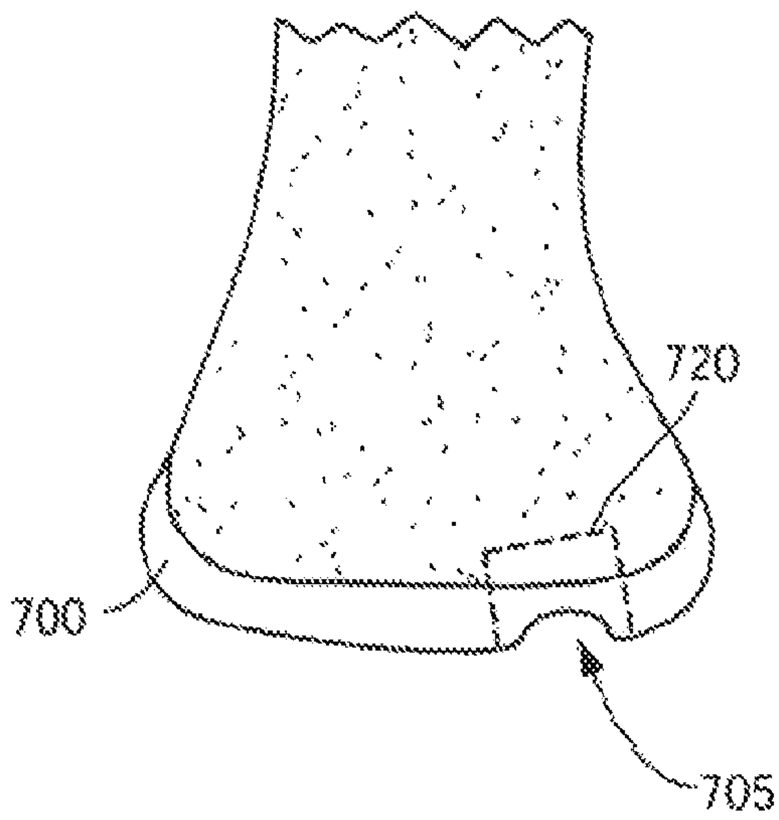


FIG. 2D

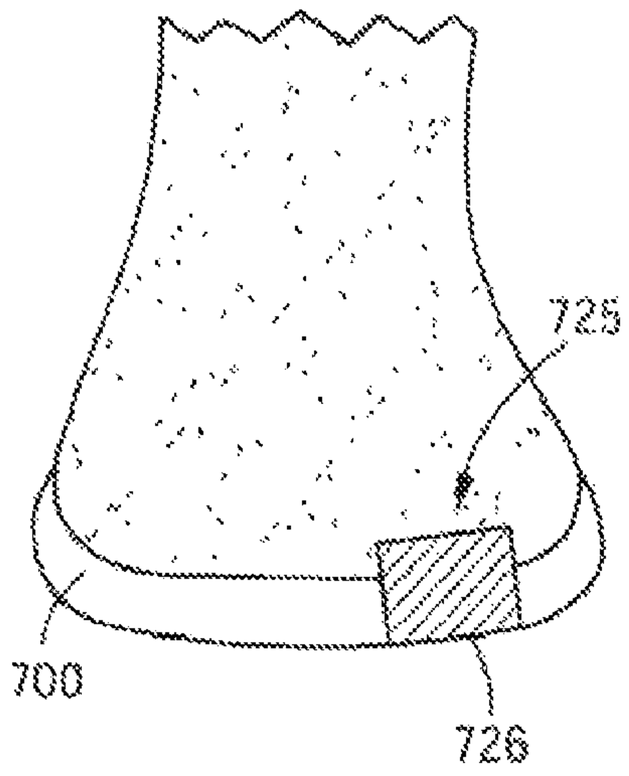


FIG. 2E

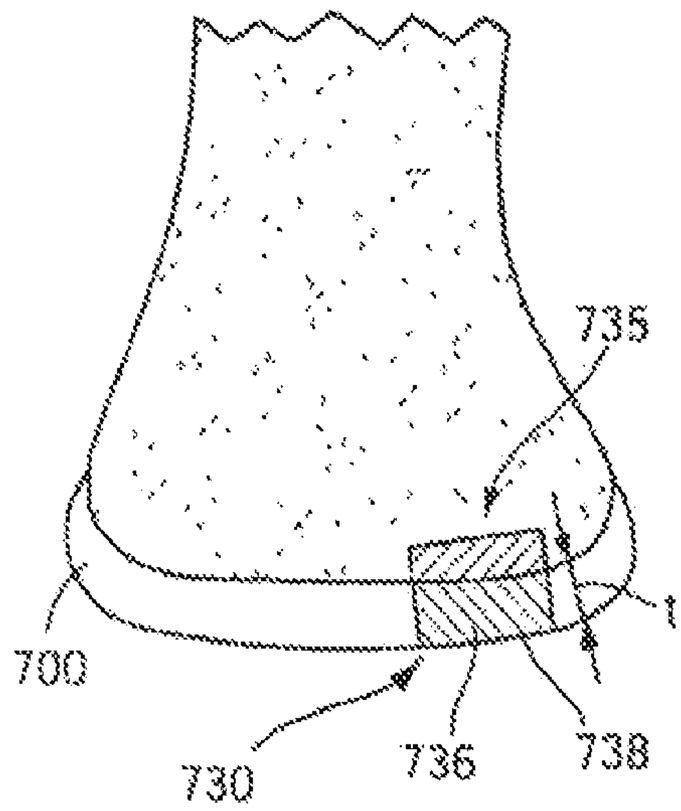


FIG. 2F

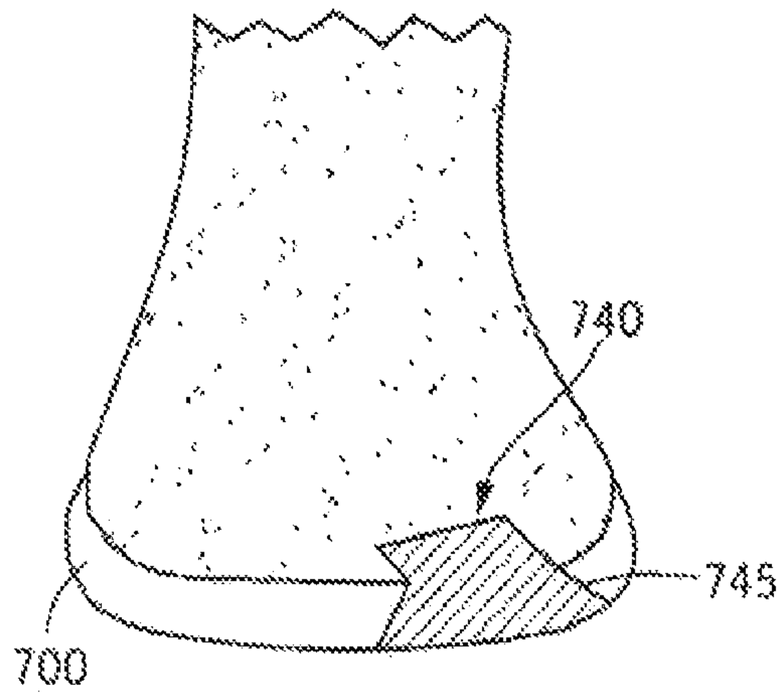


FIG. 2G

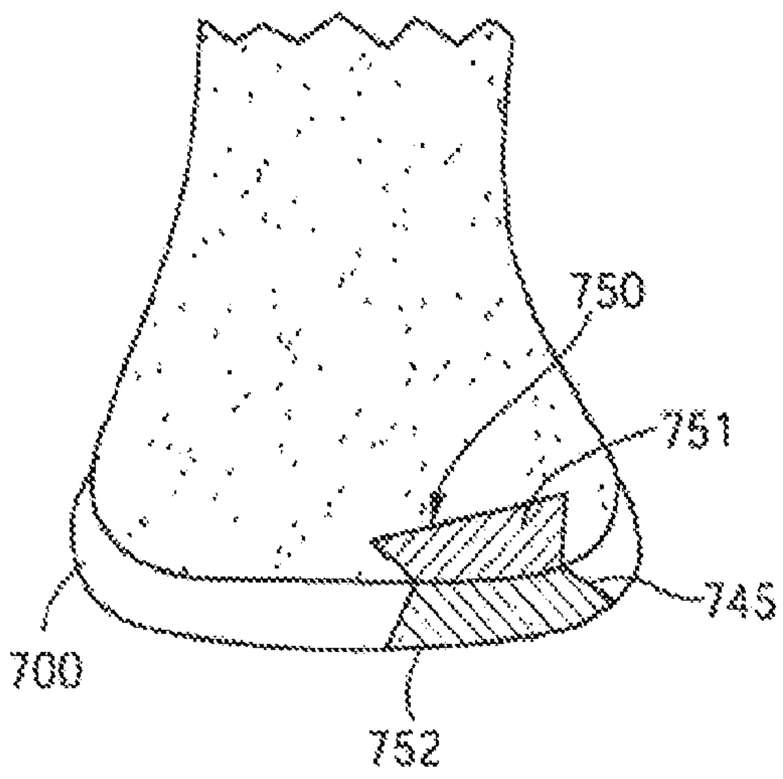


FIG. 2H

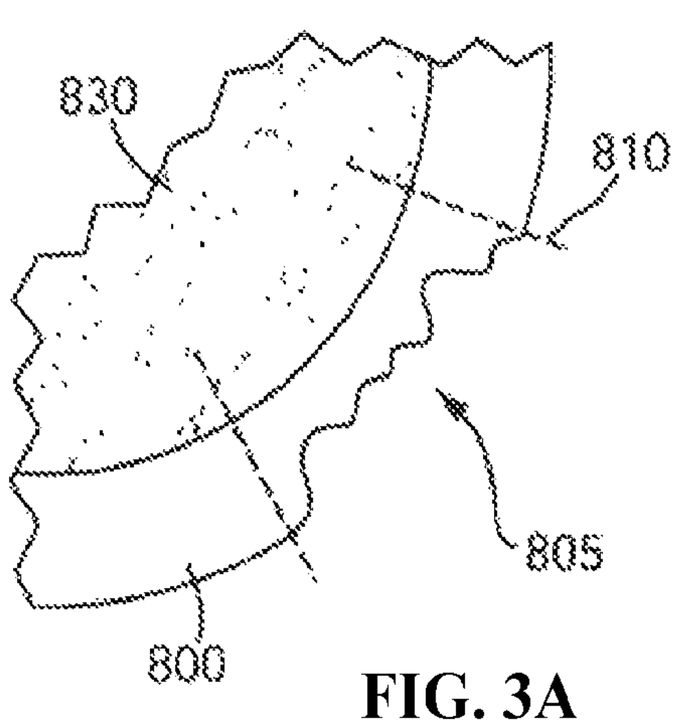


FIG. 3A

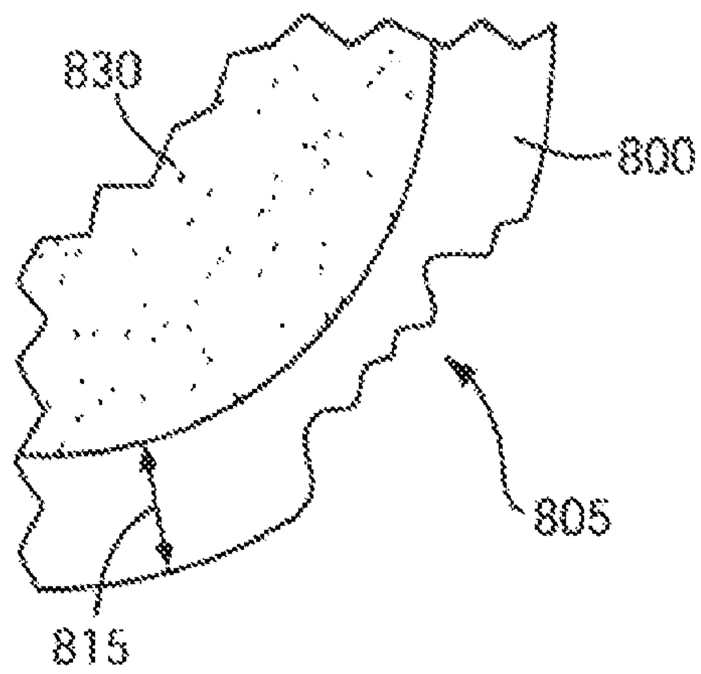


FIG. 3B

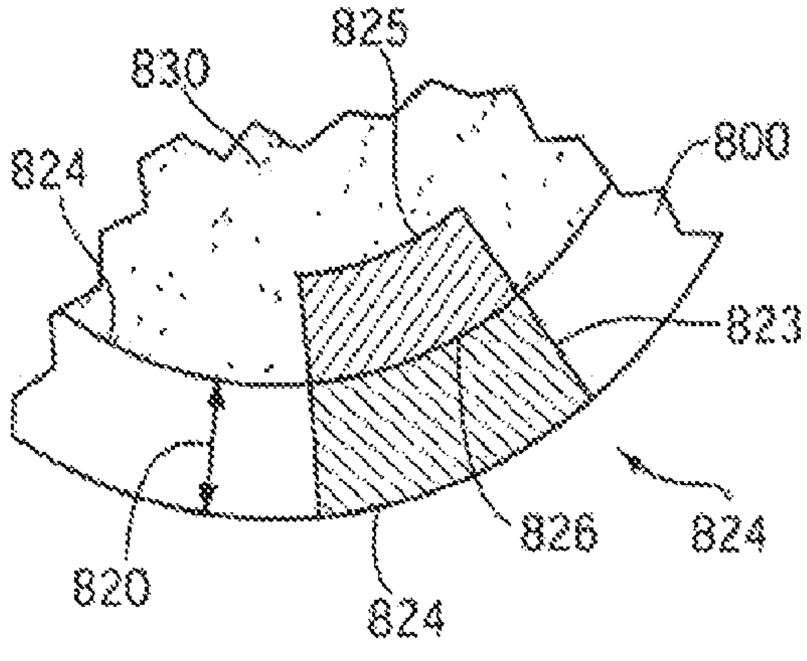


FIG. 3C

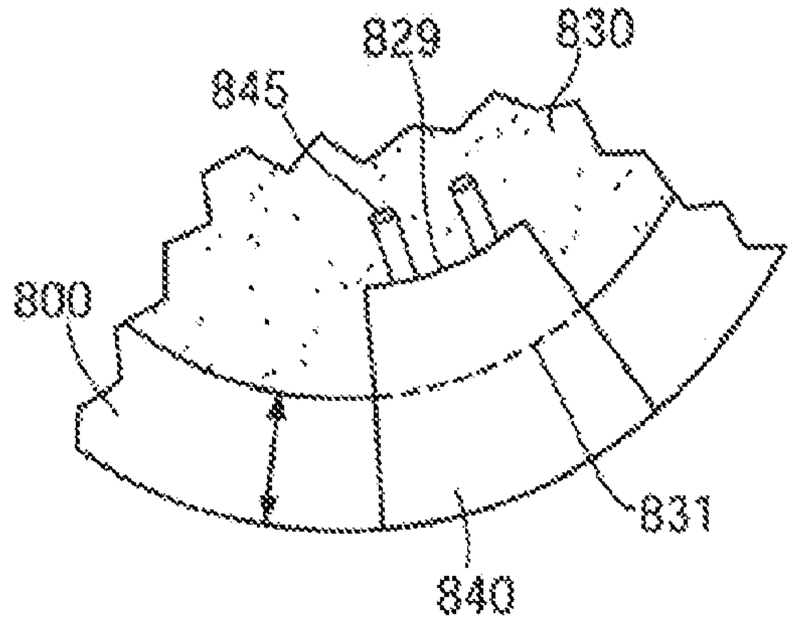


FIG. 3D

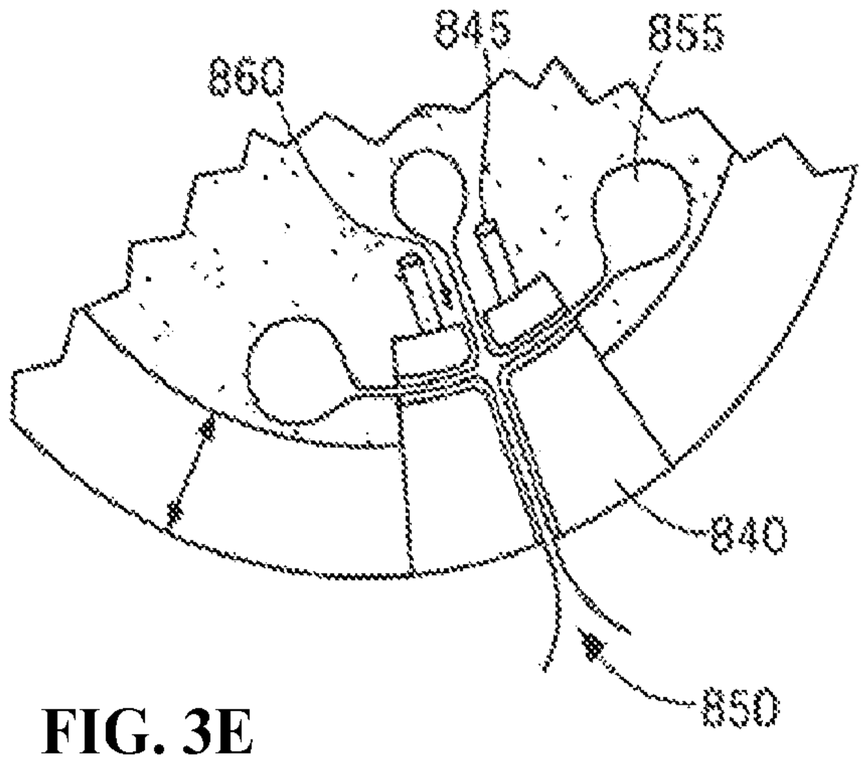


FIG. 3E

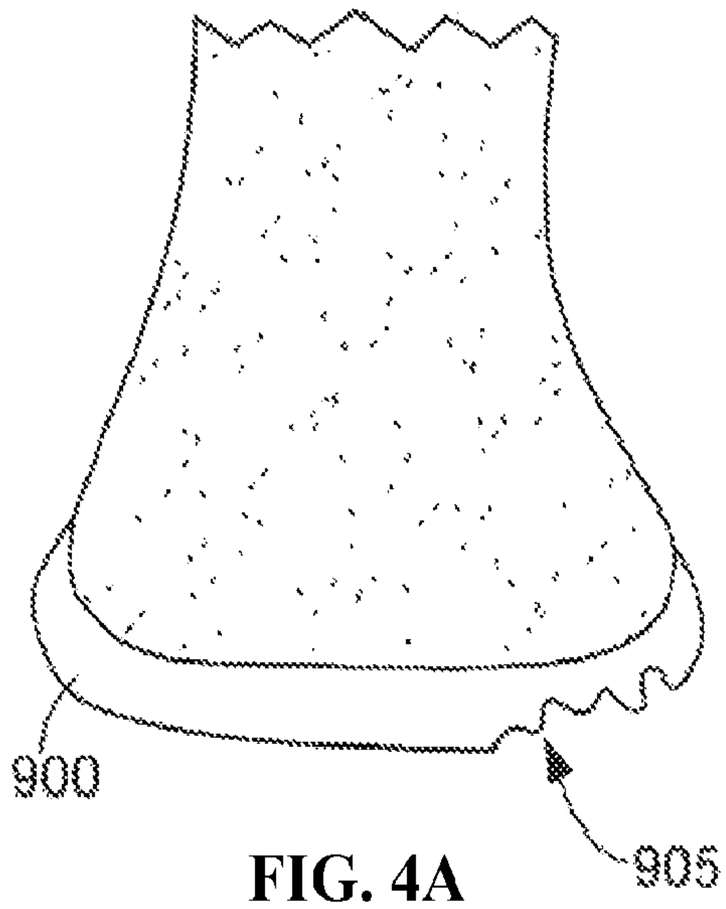


FIG. 4A

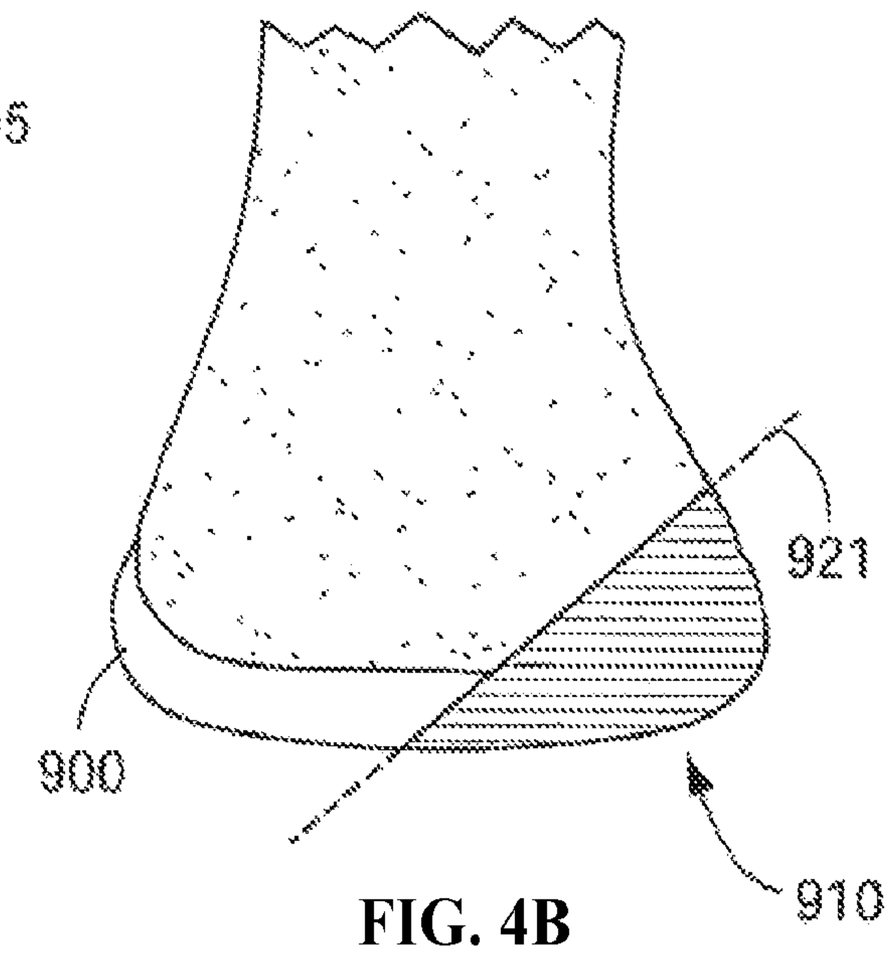


FIG. 4B

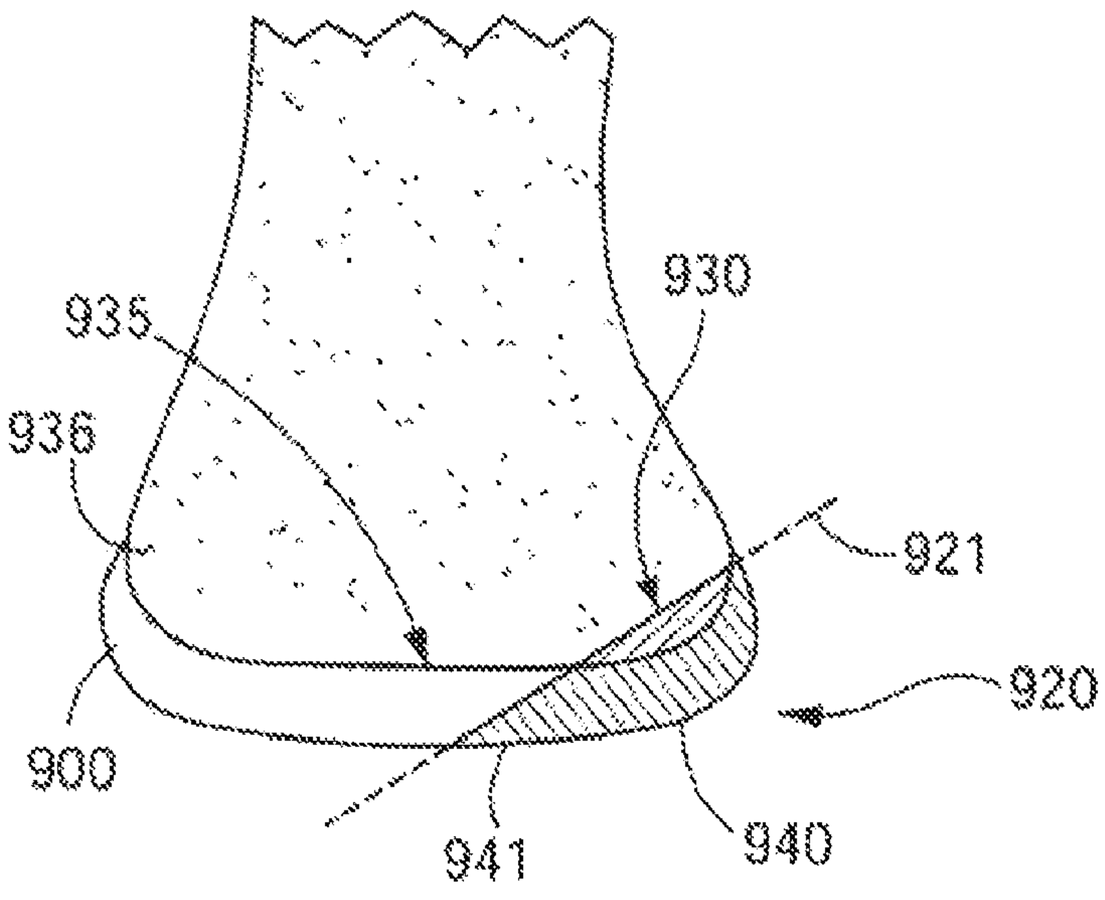


FIG. 4C

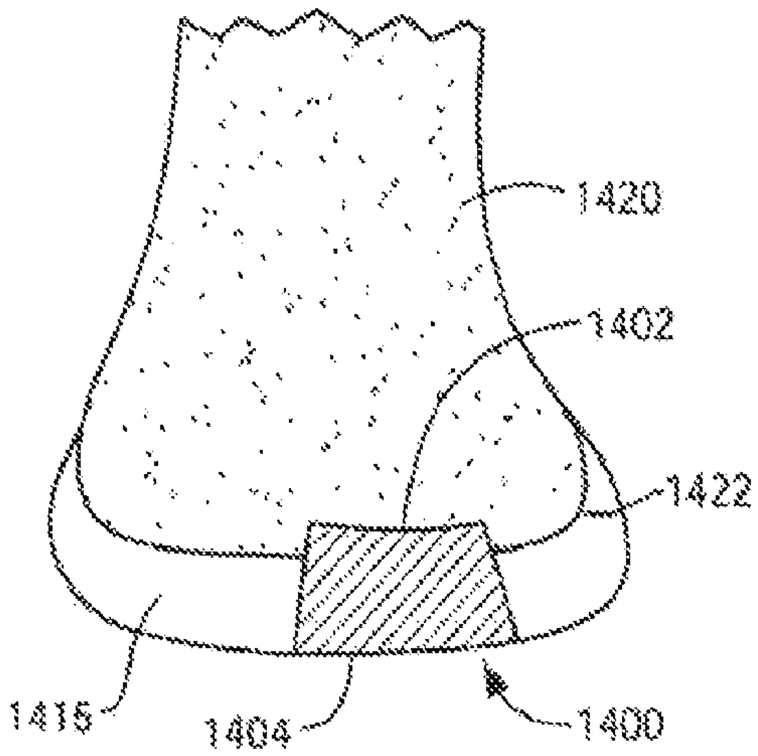


FIG. 5A

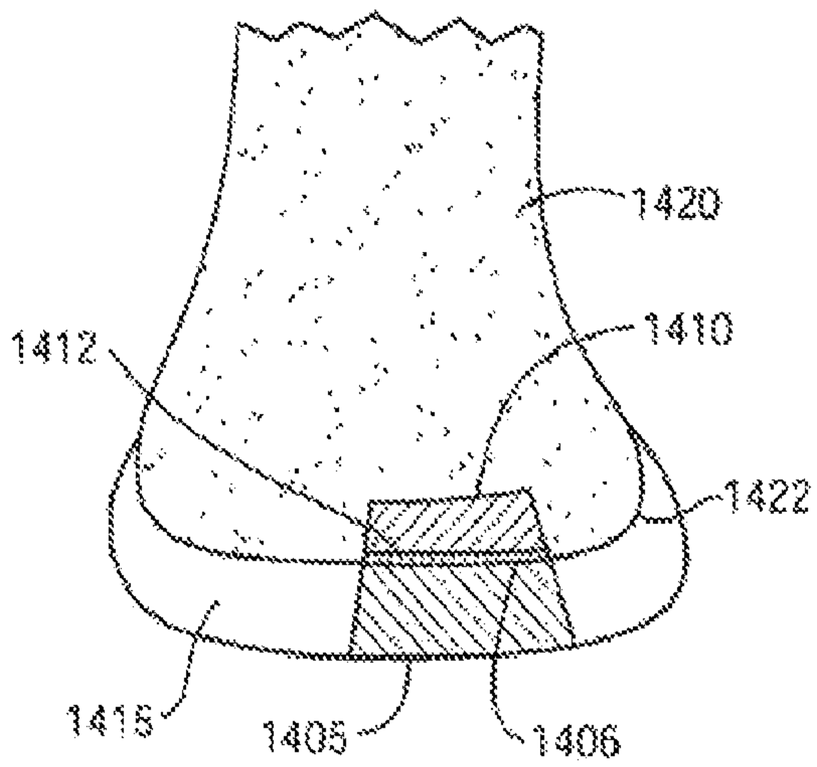


FIG. 5B

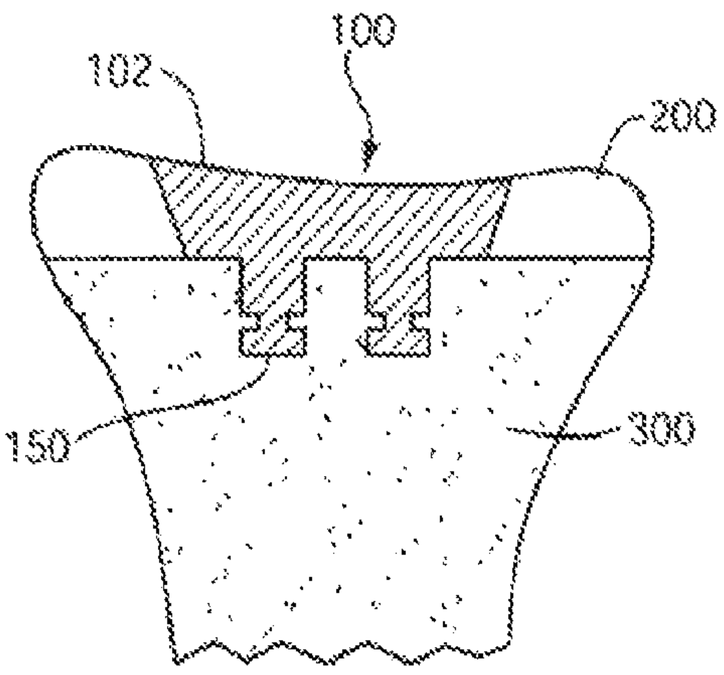


FIG. 6A

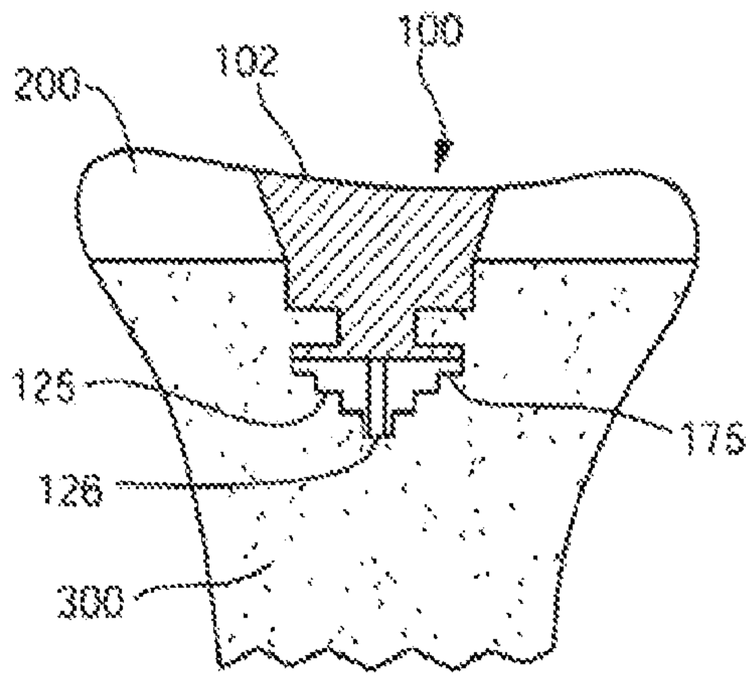


FIG. 6B

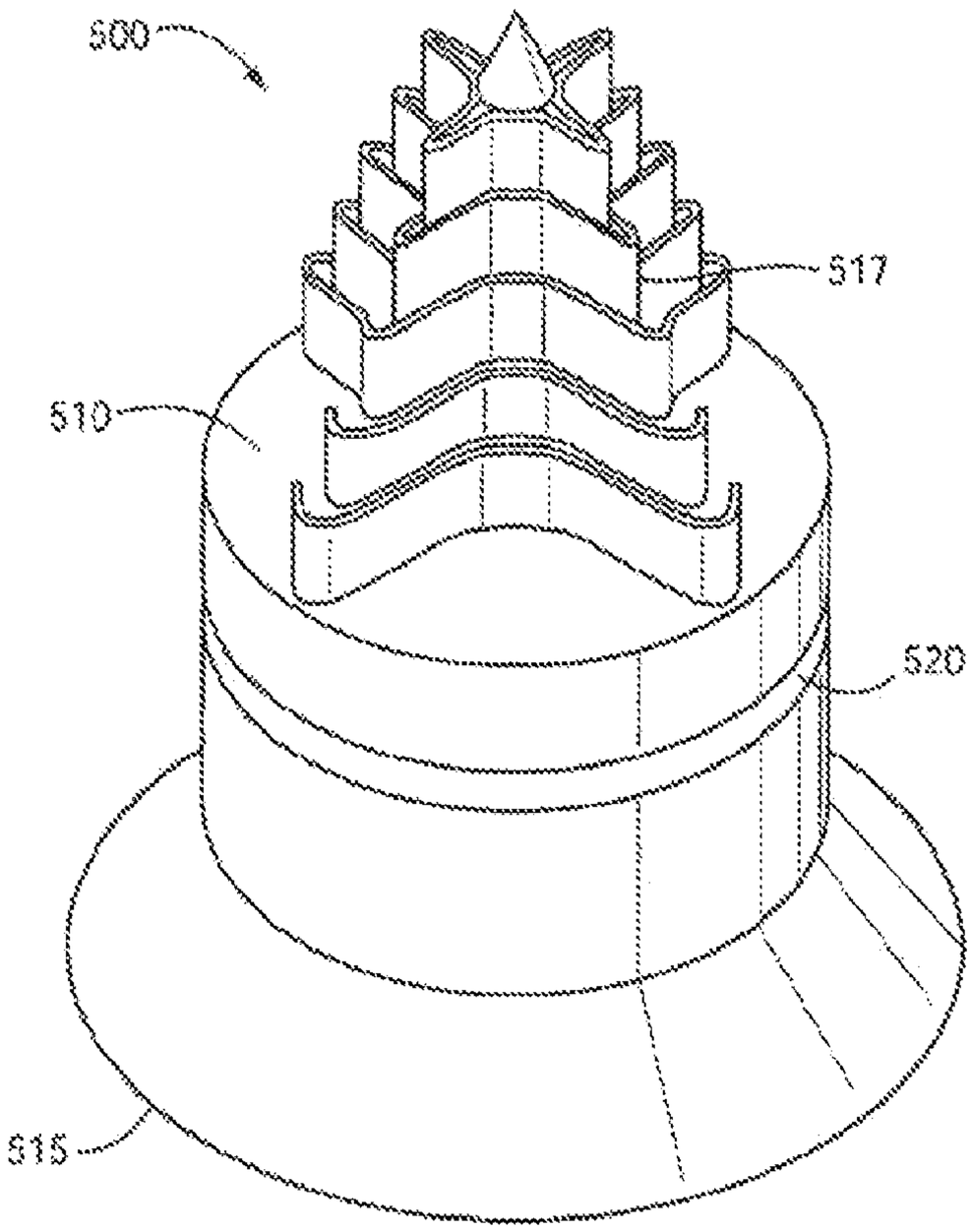


FIG. 7

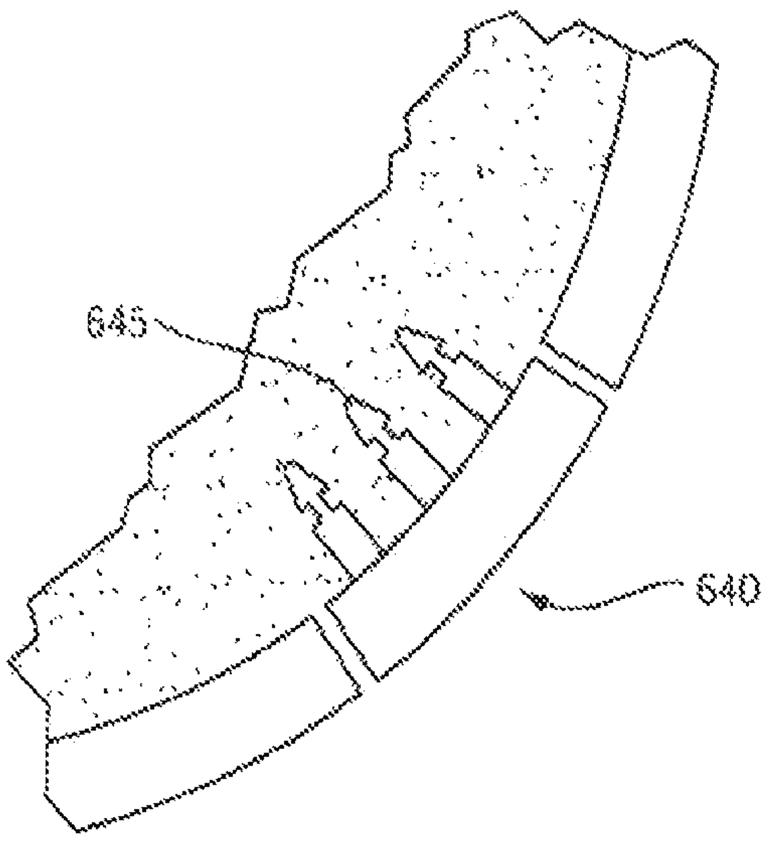


FIG. 8A

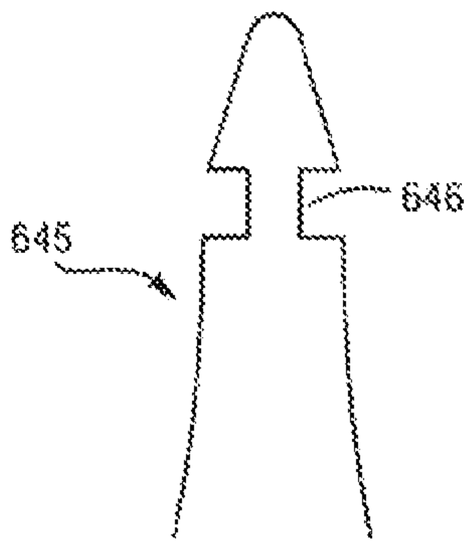
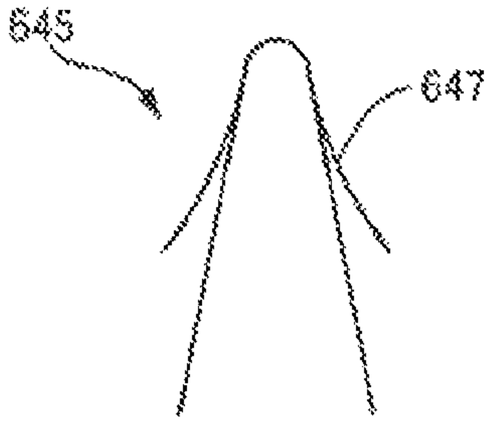


FIG. 8B



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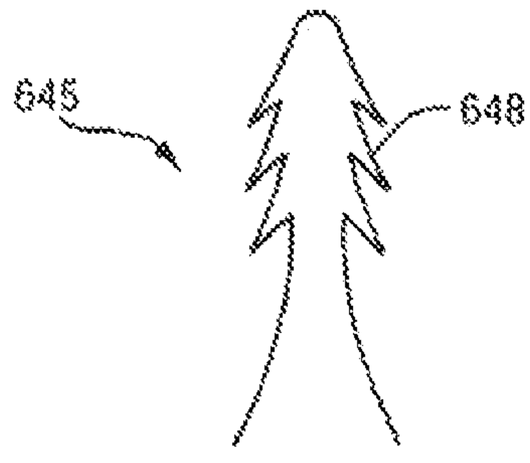


FIG. 8D

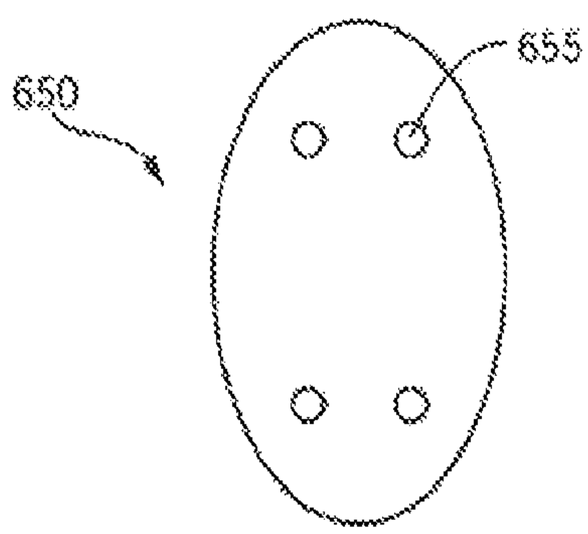


FIG. 9A

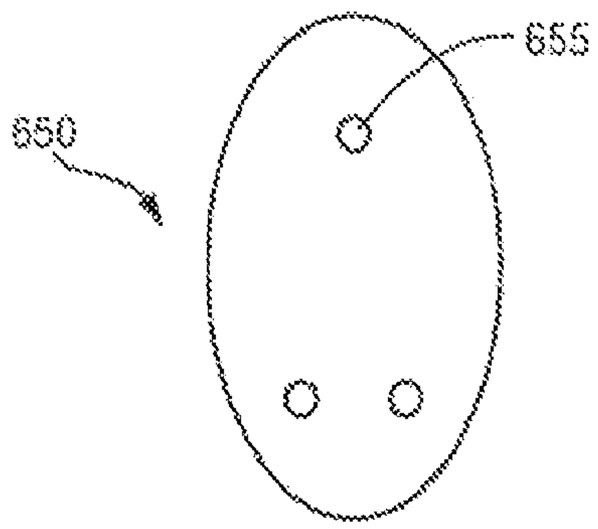


FIG. 9B

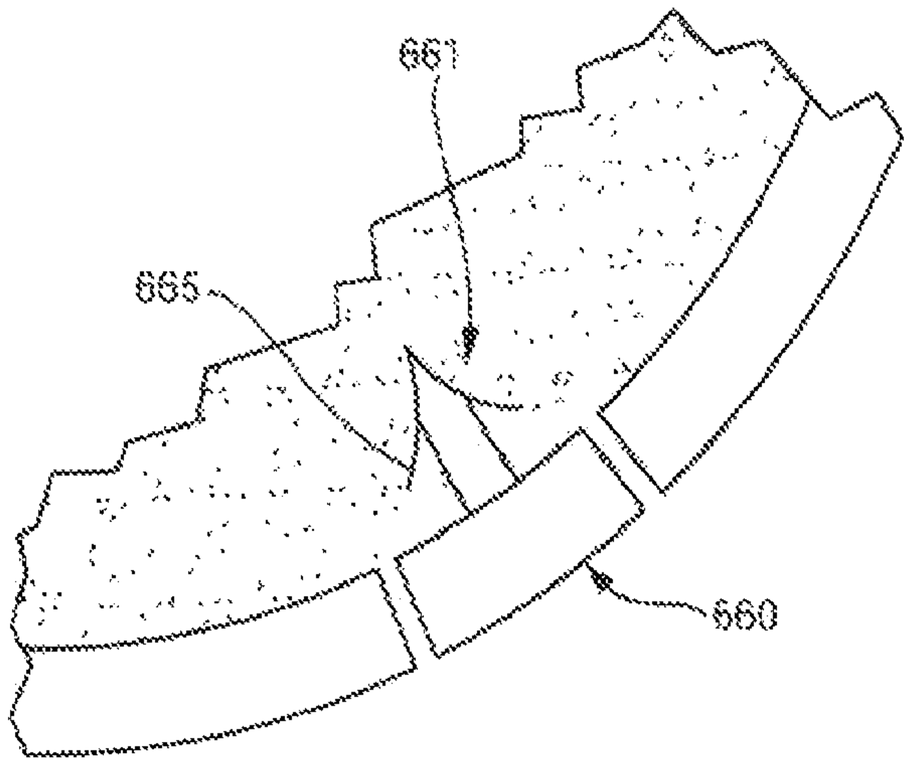
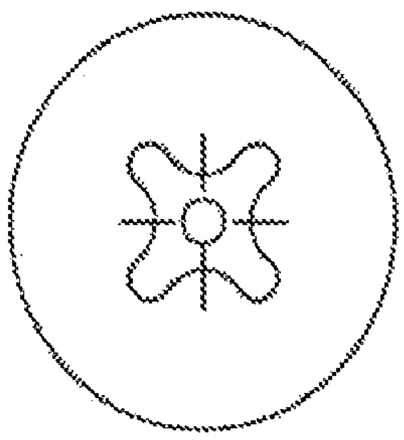


FIG. 10A

FIG. 10B



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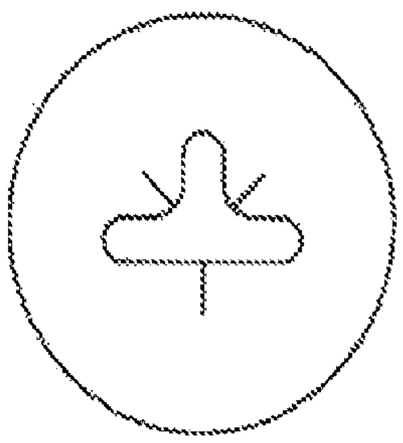

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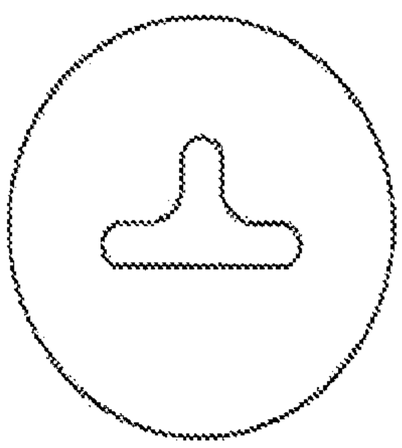


FIG. 10E

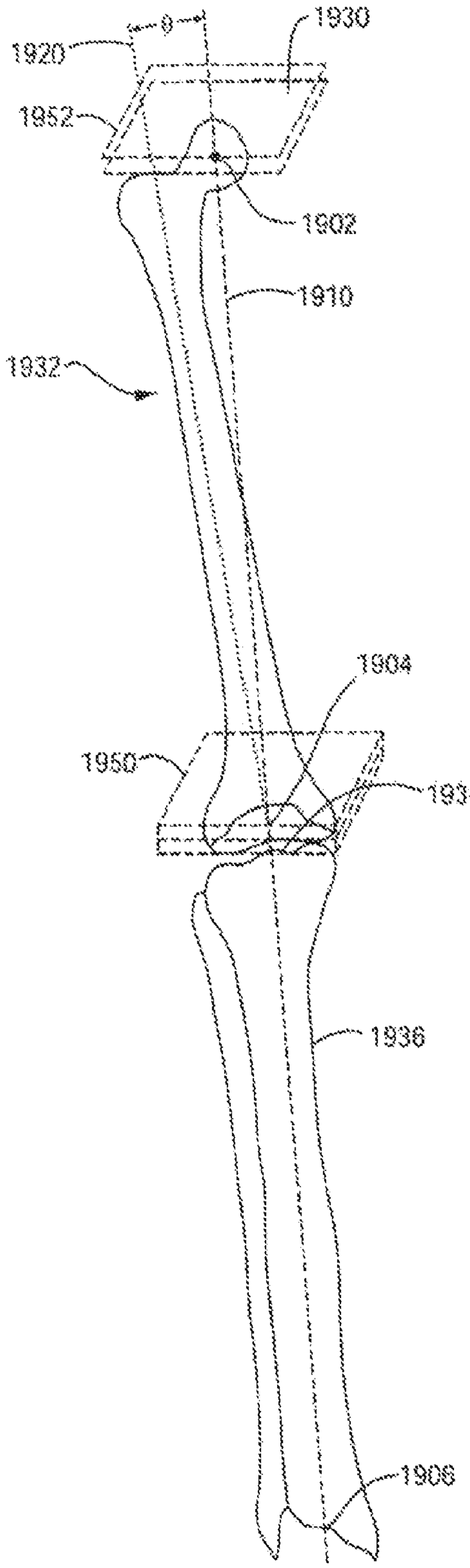


FIG. 11A

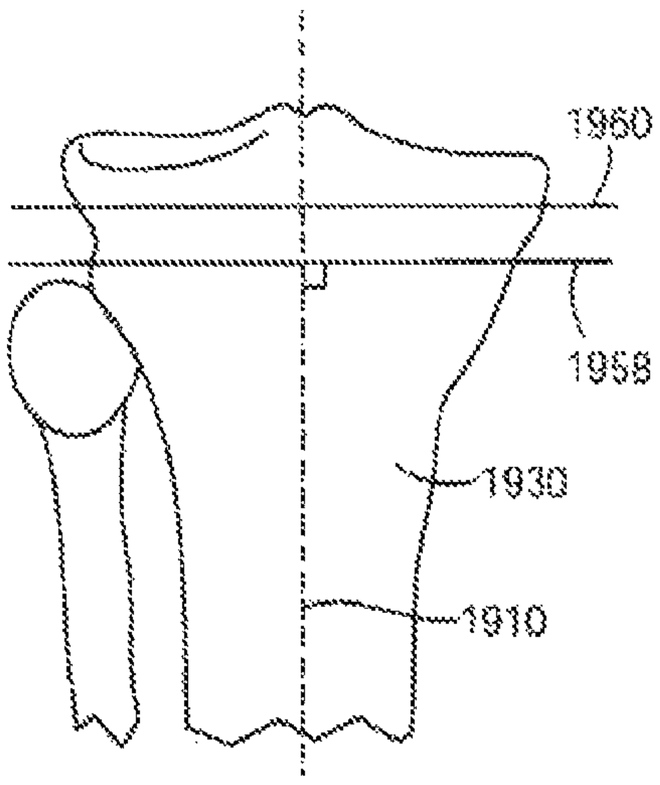
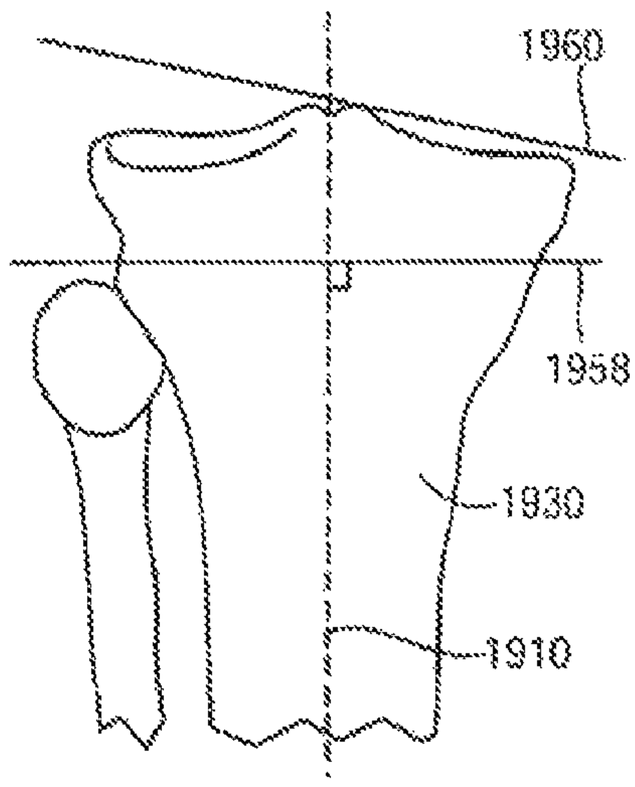


FIG. 11B



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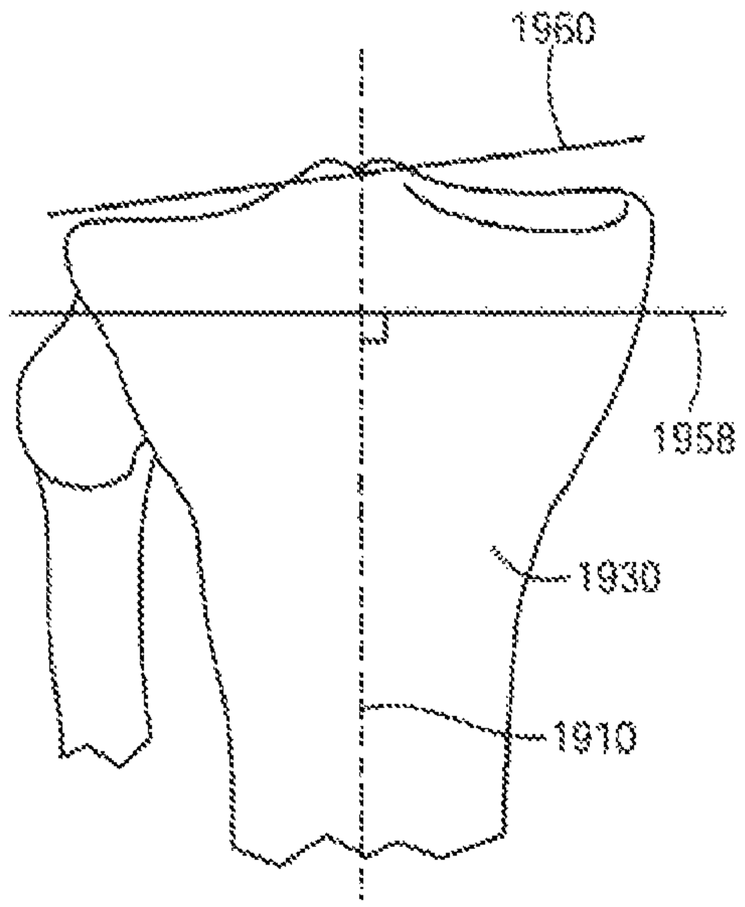


FIG. 11D

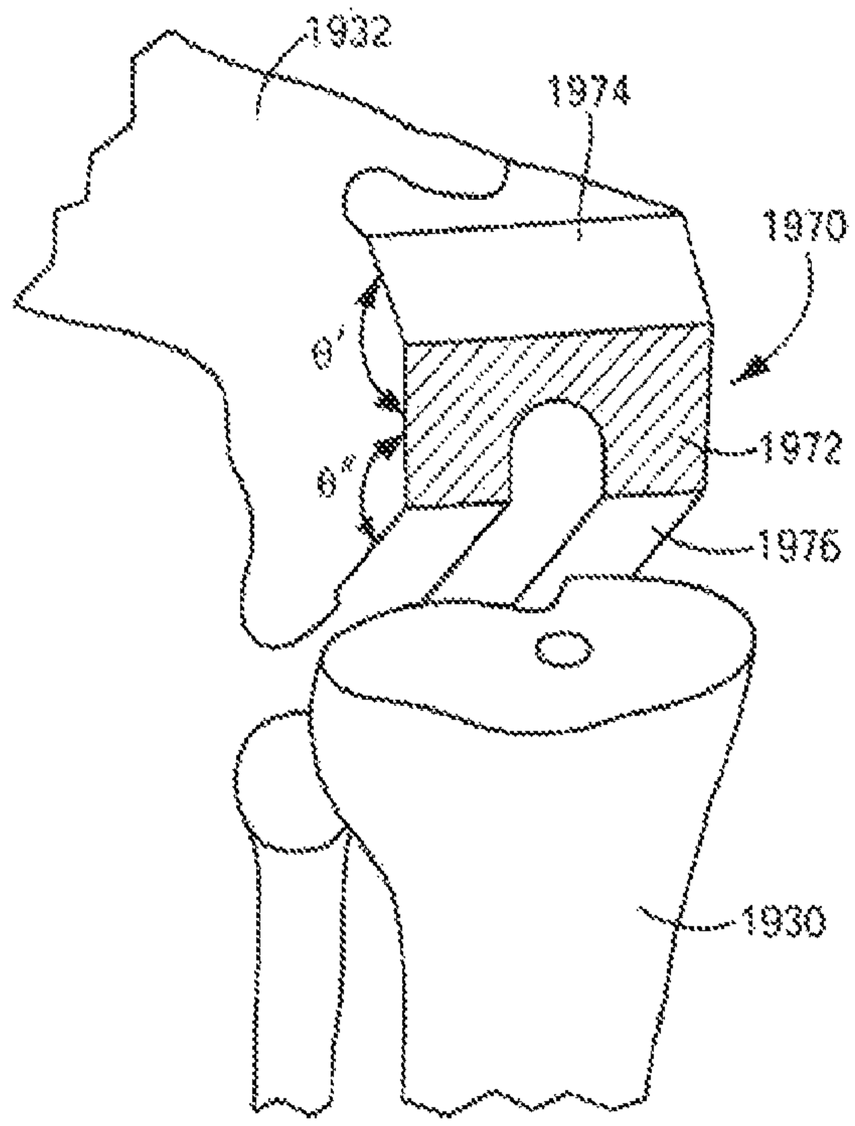


FIG. 11E

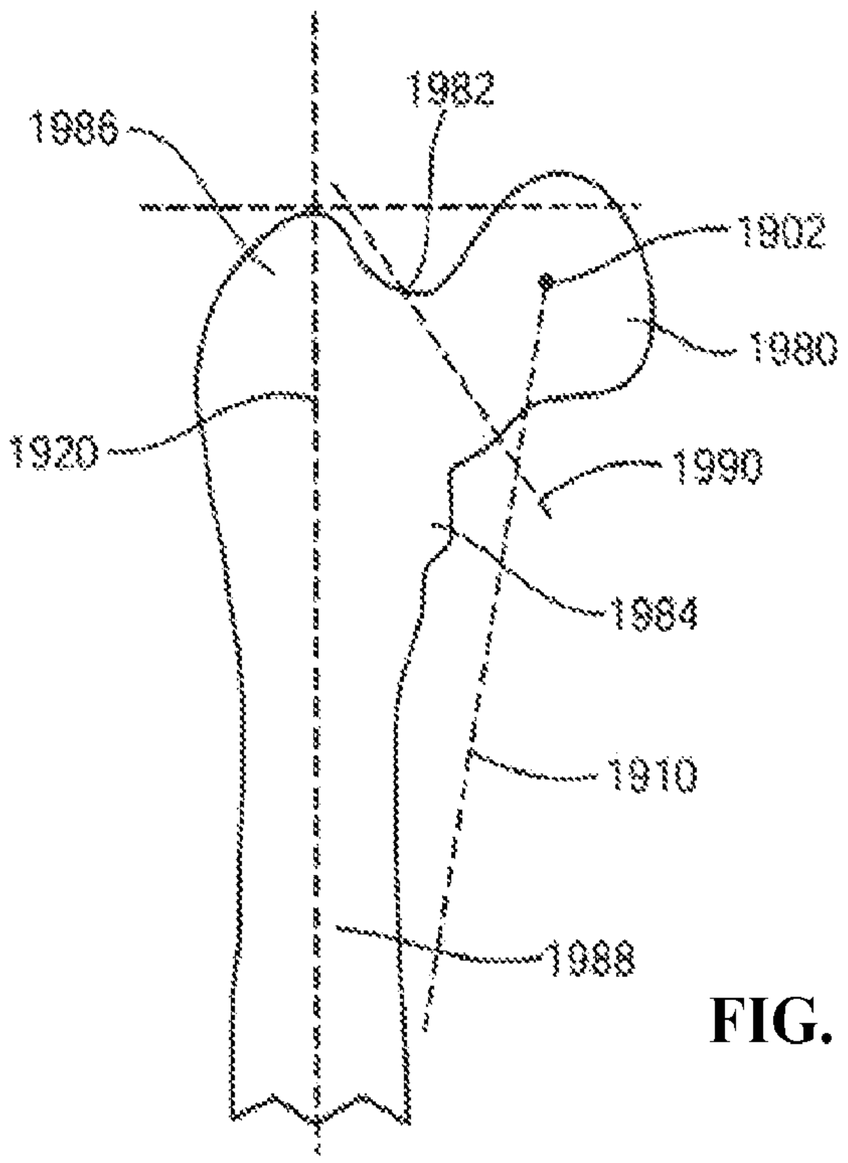


FIG. 11F

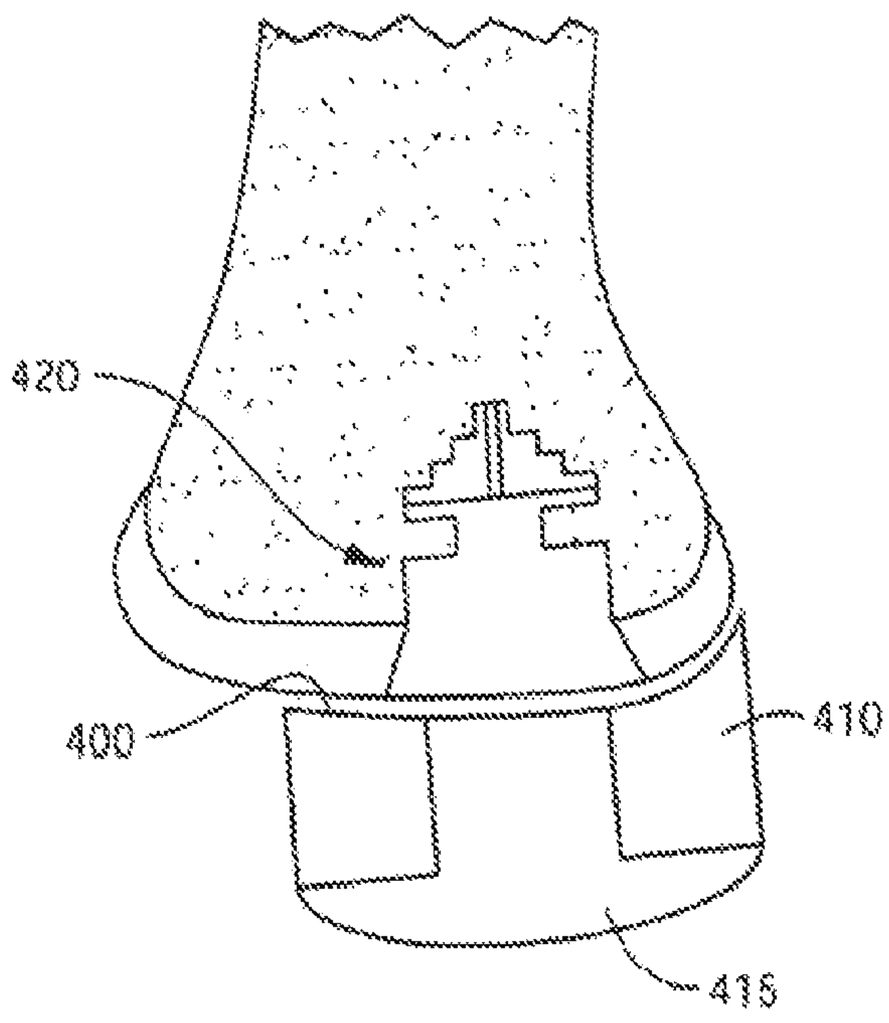


FIG. 12

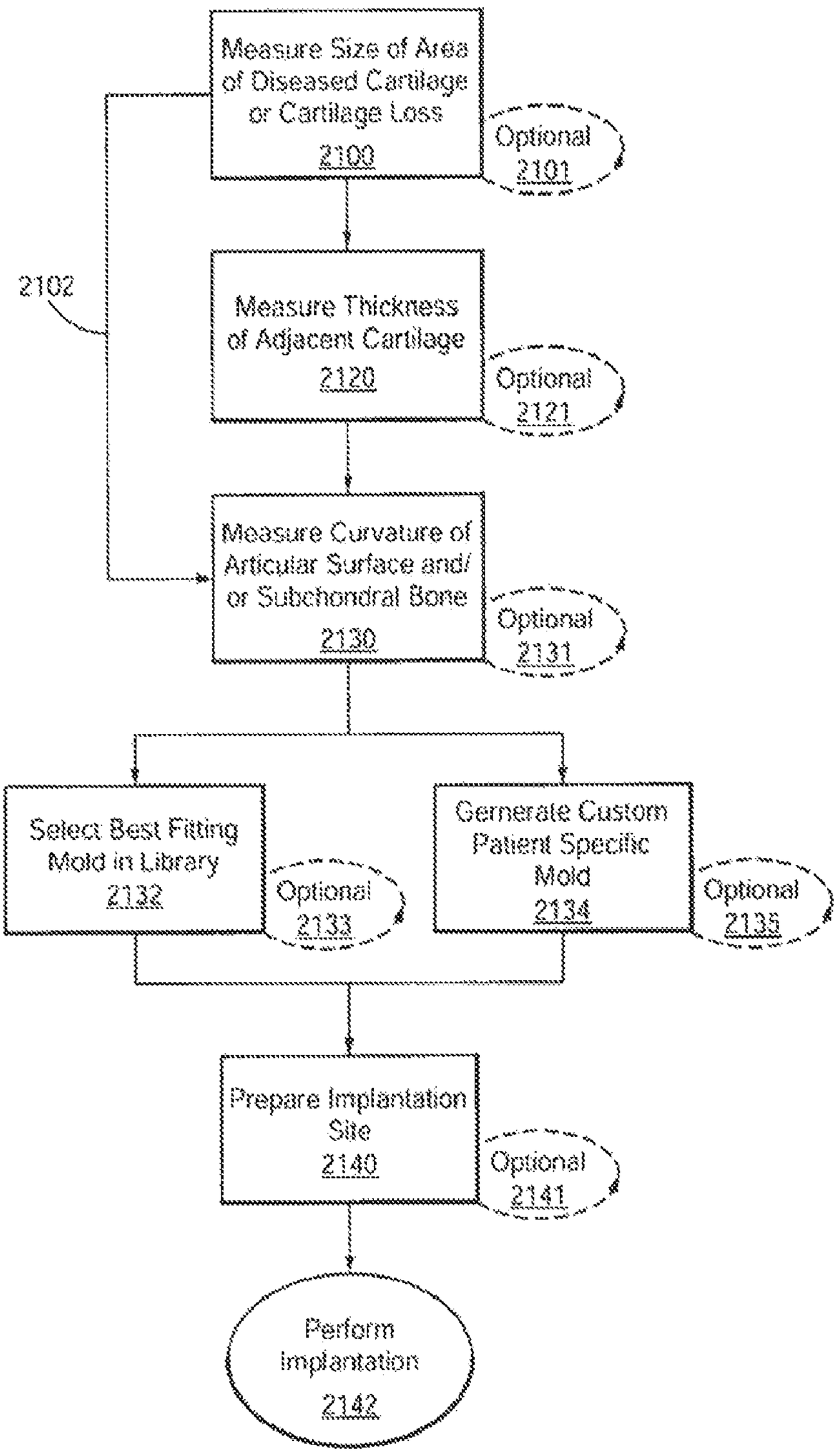

Measure Size of Area of Diseased Cartilage or Cartilage Loss
2100
Optional
2101
2102
Measure Thickness of Adjacent Cartilage
2120
Optional
2121
Measure Curvature of Articular Surface and/or Subchondral Bone
2130
Optional
2131
Select Best Fitting Mold in Library
2132
Optional
2133
Gernerate Custom Patient Specific Mold
2134
Optional
2135
Prepare Implantation Site
2140
Optional
2141
Perform Implantation
2142

FIG. 13

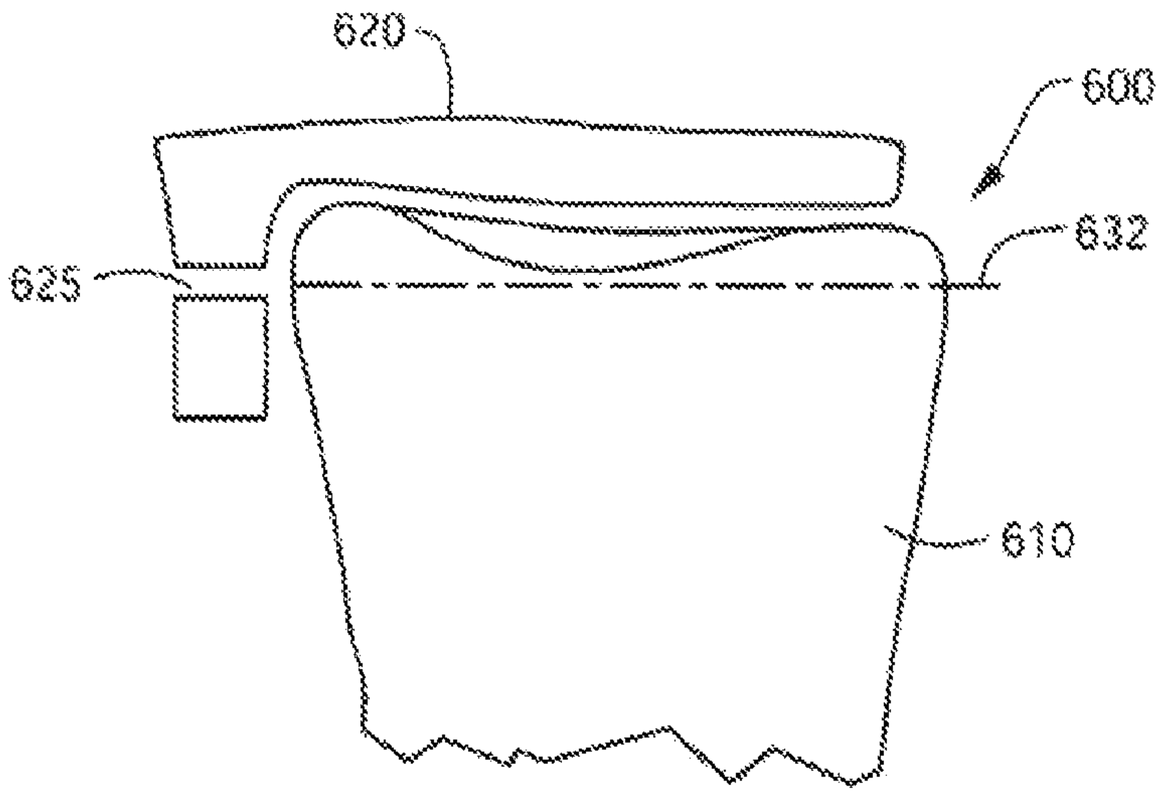


FIG. 14A

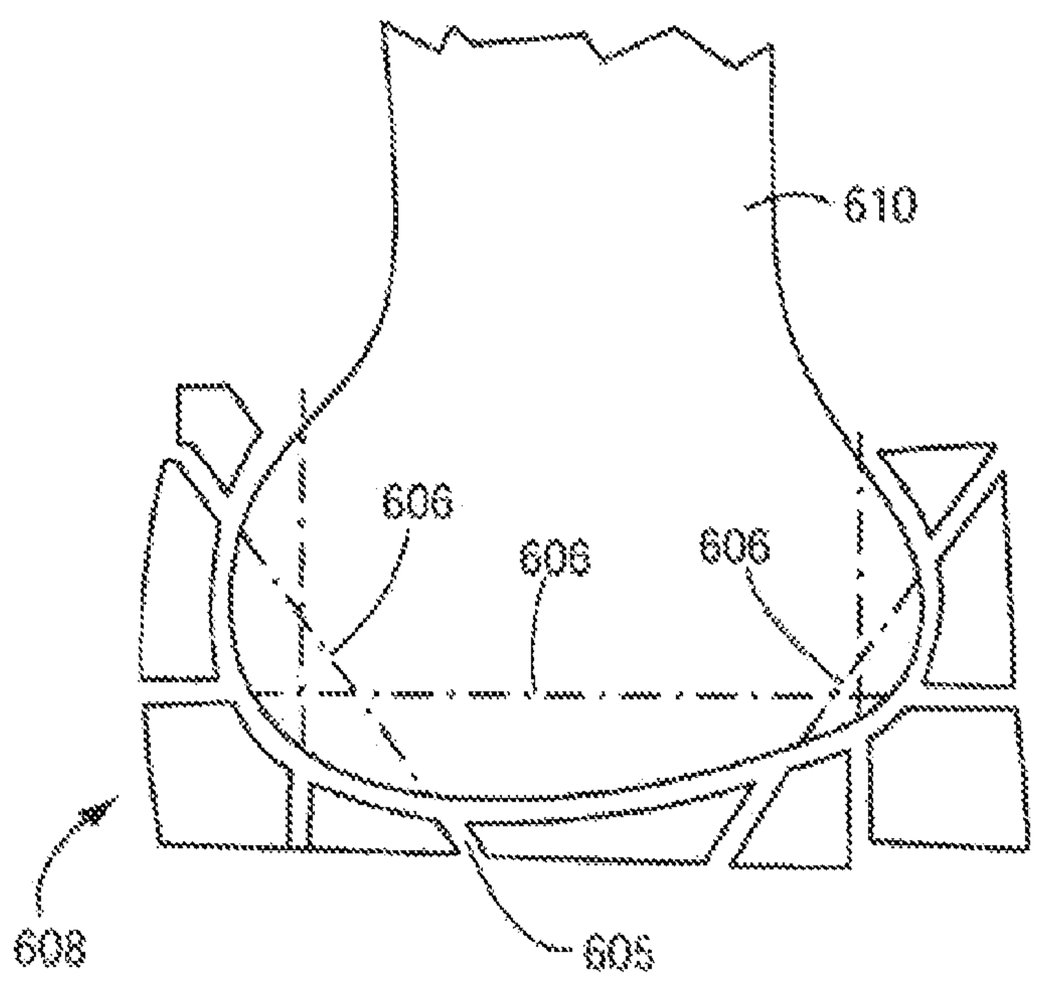


FIG. 14B

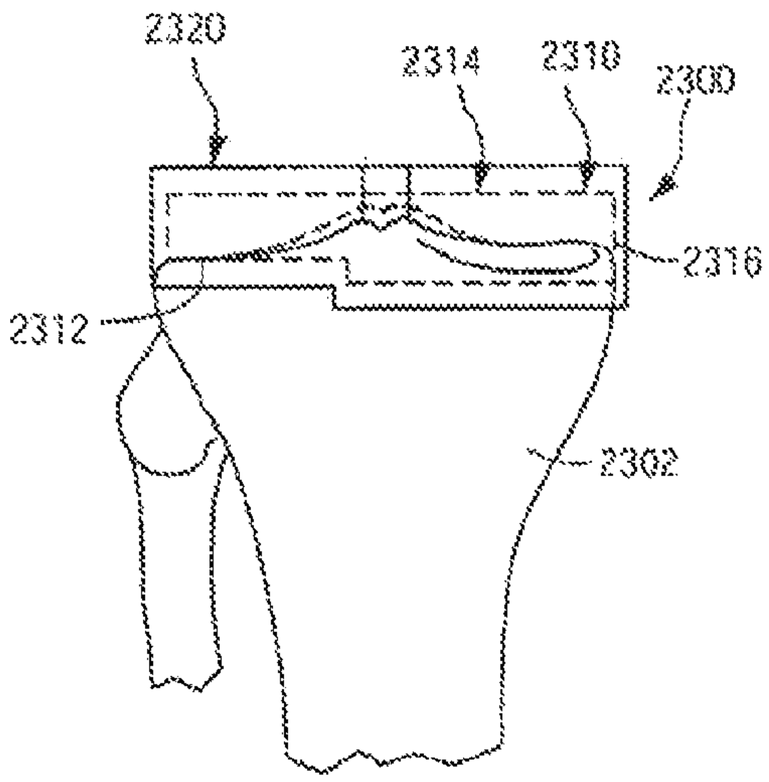


FIG. 15A

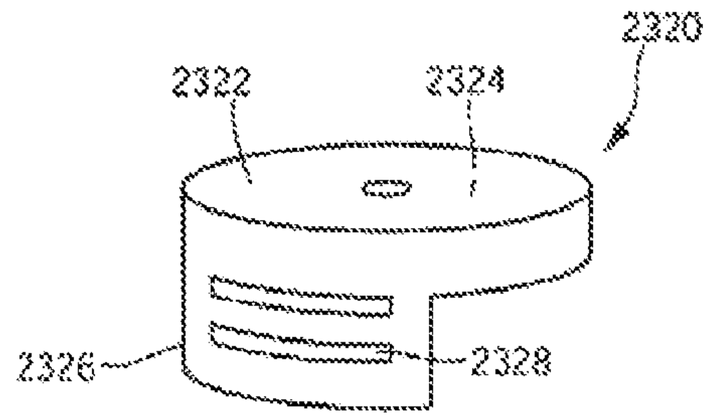


FIG. 15B

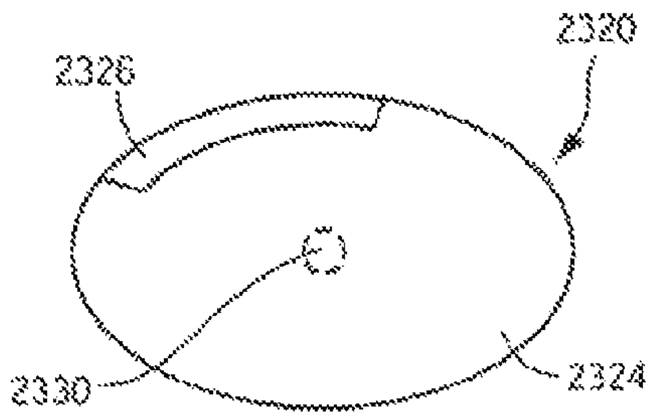


FIG. 15C

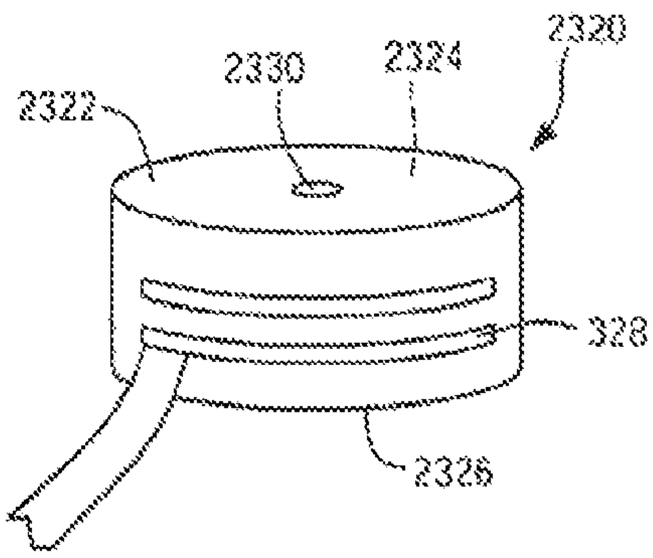


FIG. 15D

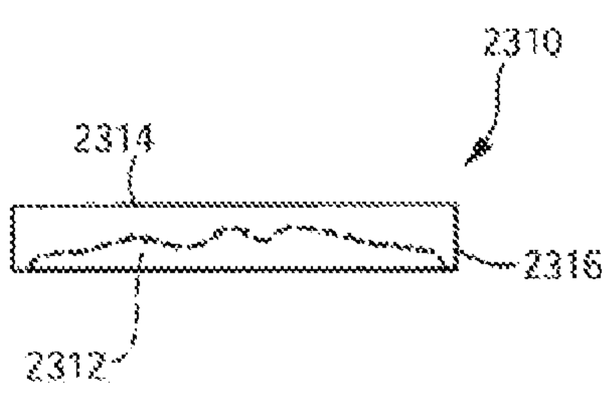


FIG. 15E

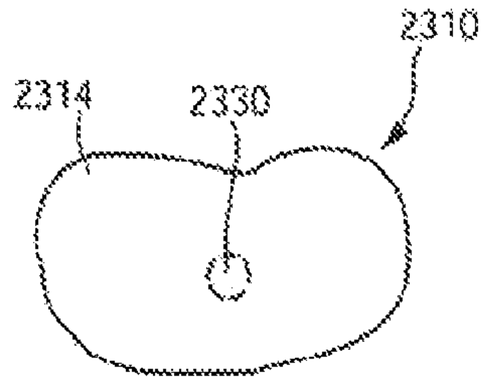


FIG. 15F

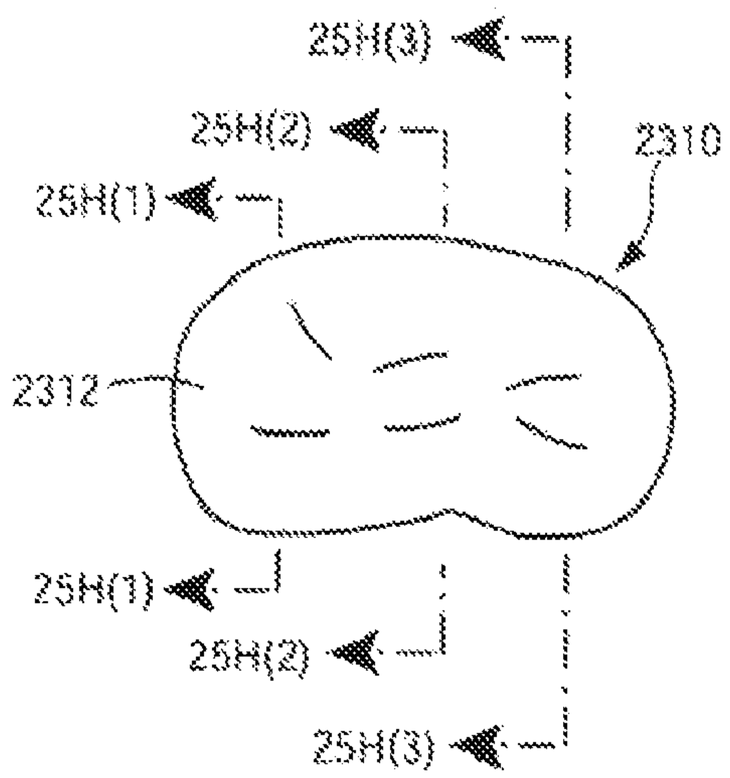


FIG. 15G

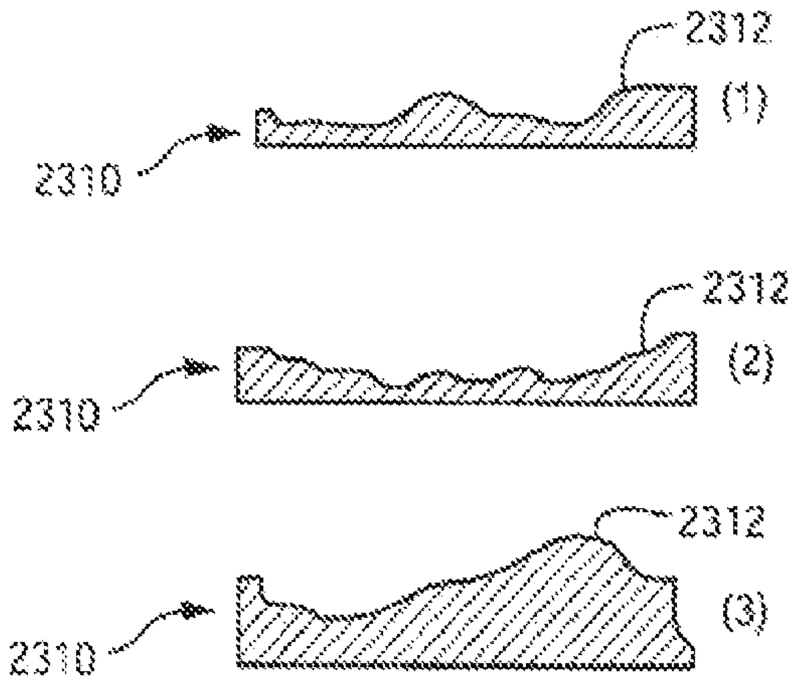


FIG. 15H

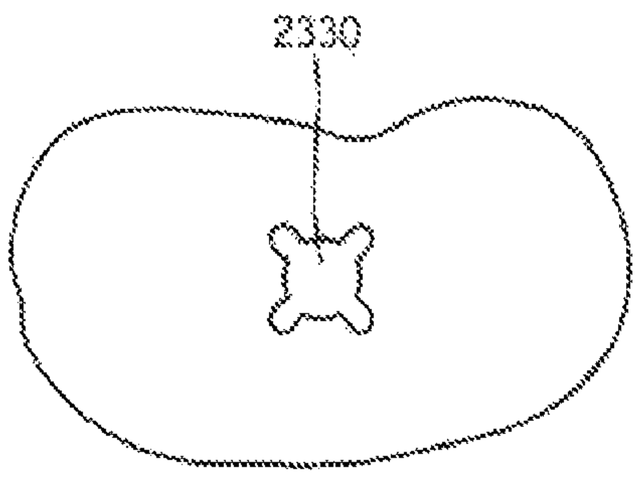


FIG. 15I

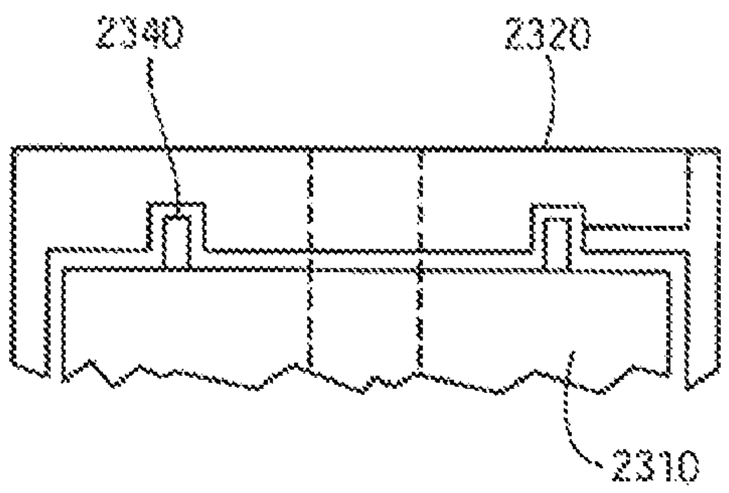


FIG. 15J

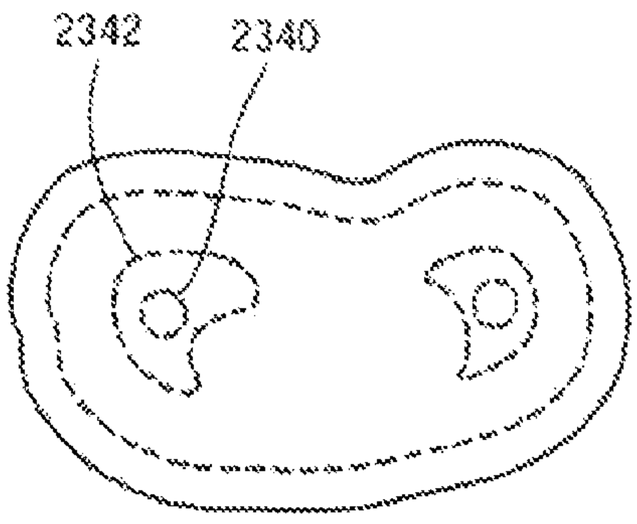


FIG. 15K

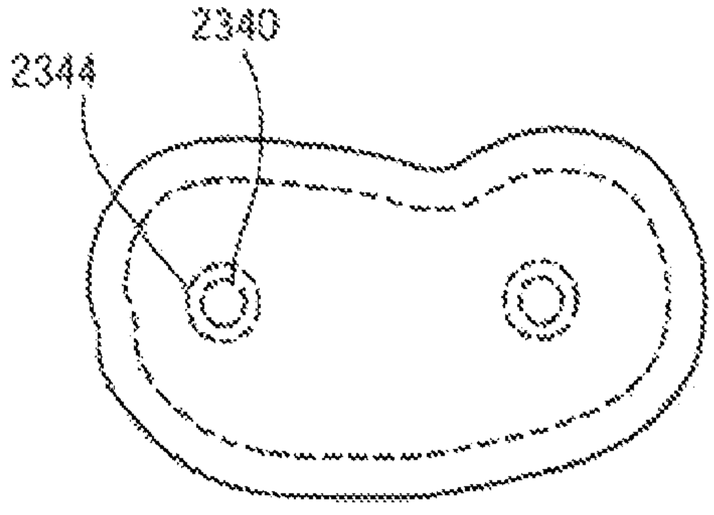


FIG. 15L

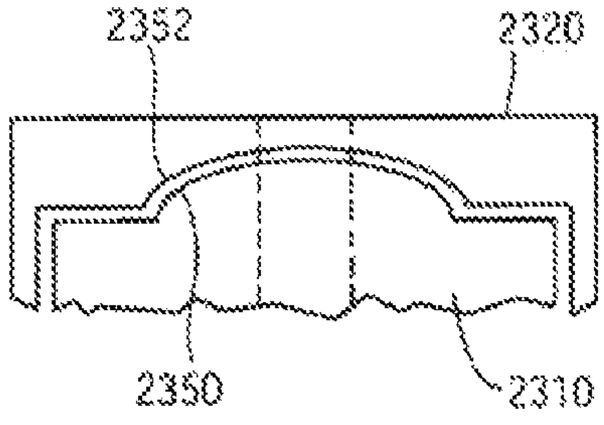


FIG. 15M

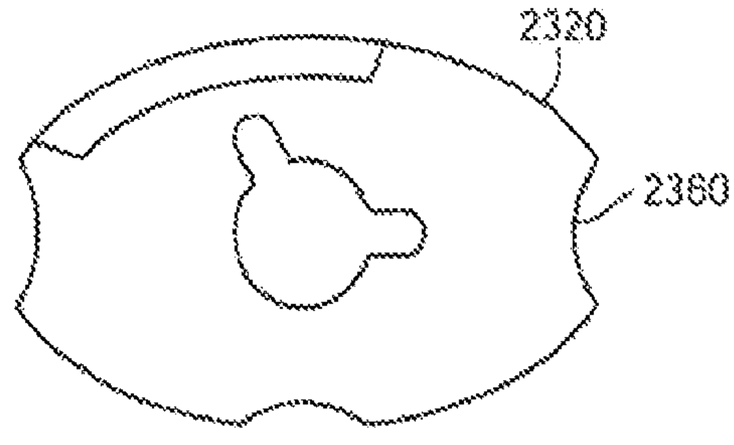


FIG. 15N

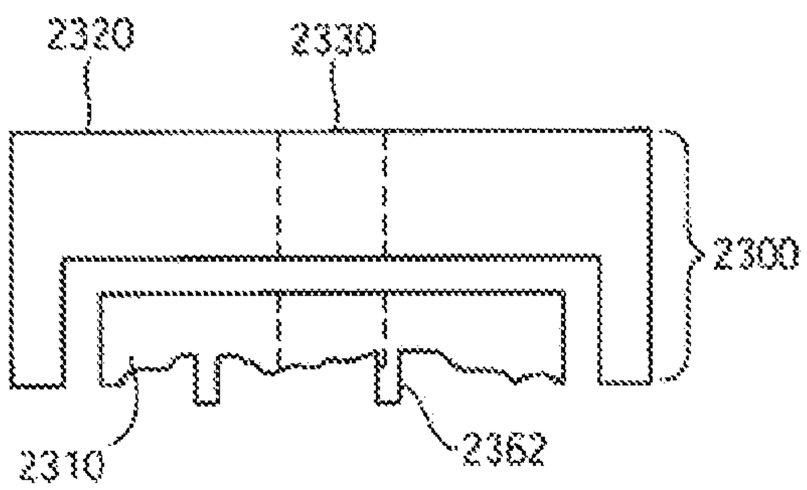


FIG. 15O

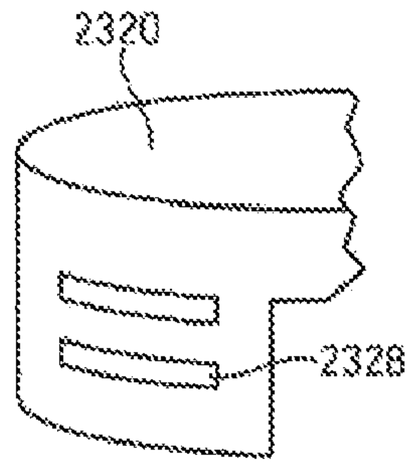


FIG. 15P

FIG. 15Q

FIG. 15R

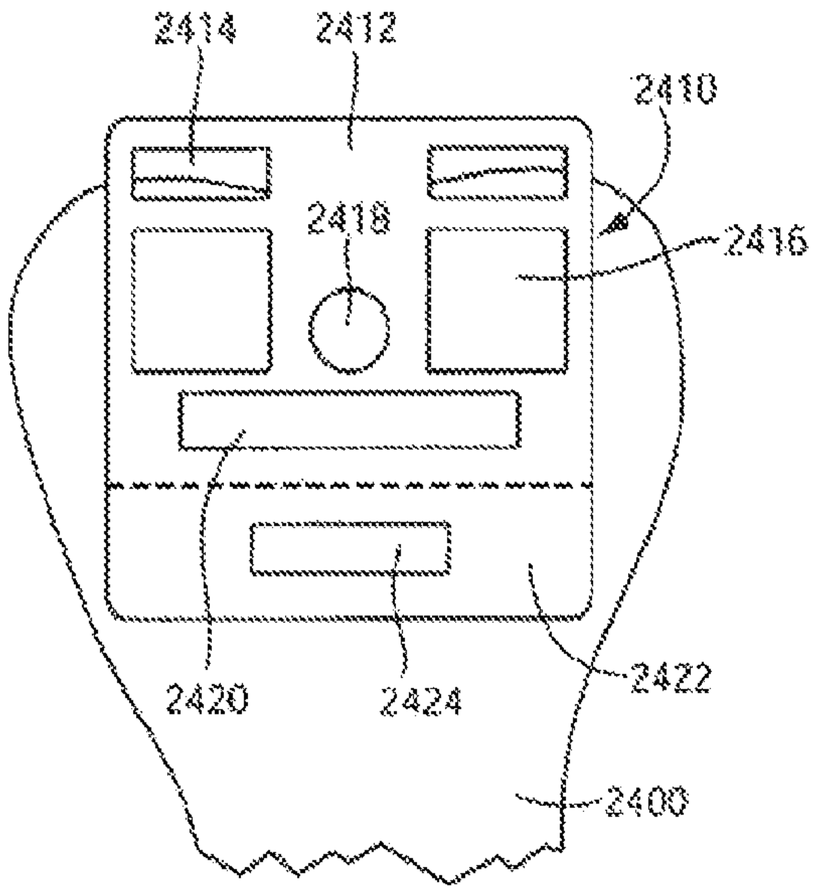


FIG. 16A

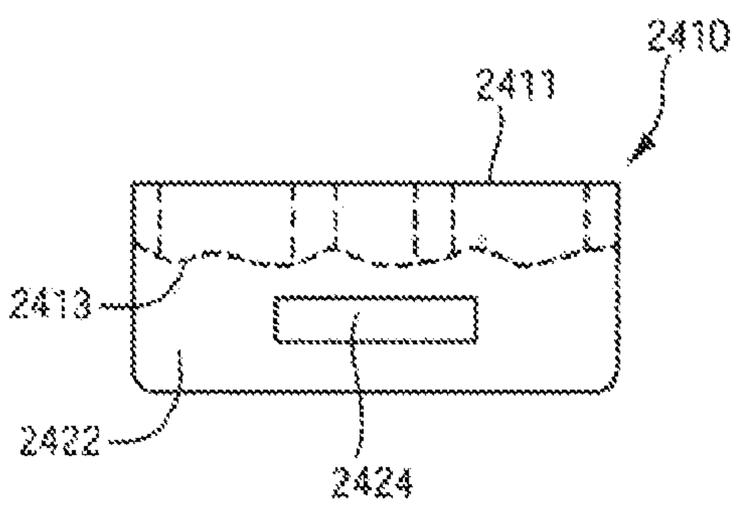


FIG. 16B

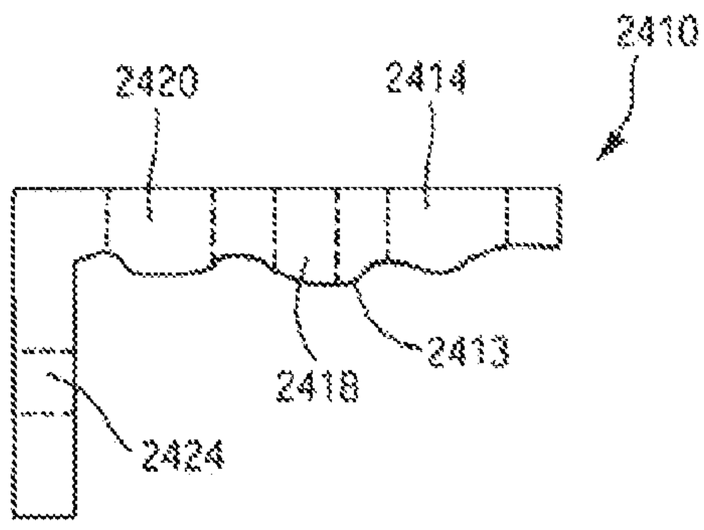


FIG. 16C

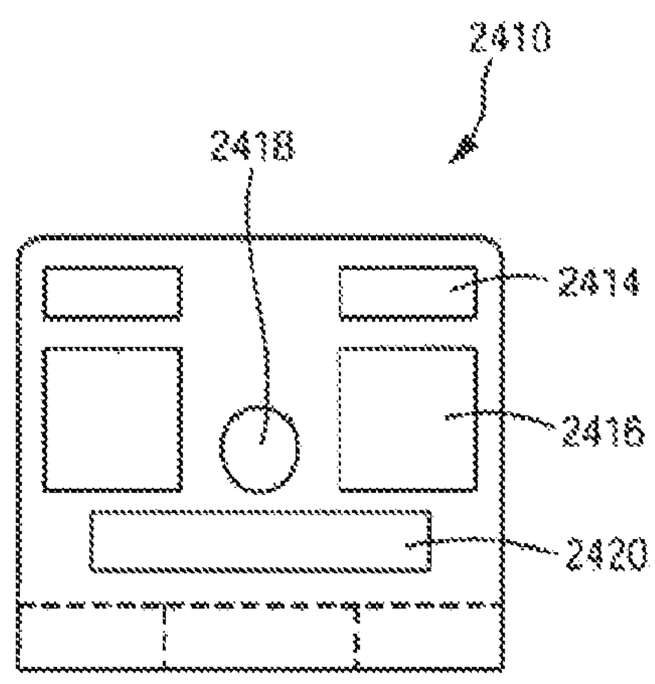


FIG. 16D

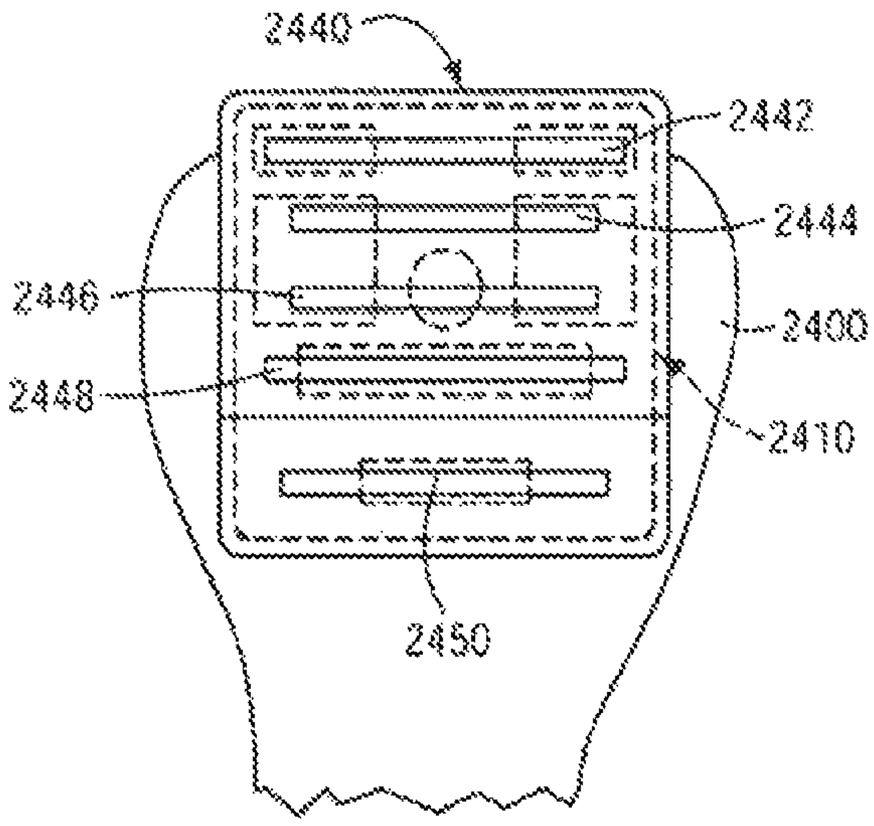


FIG. 16E

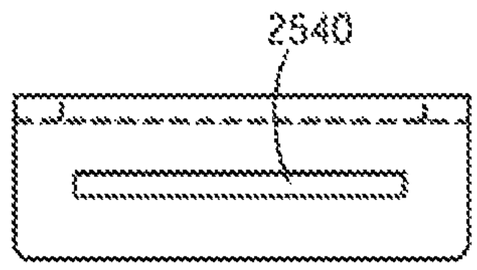


FIG. 16F

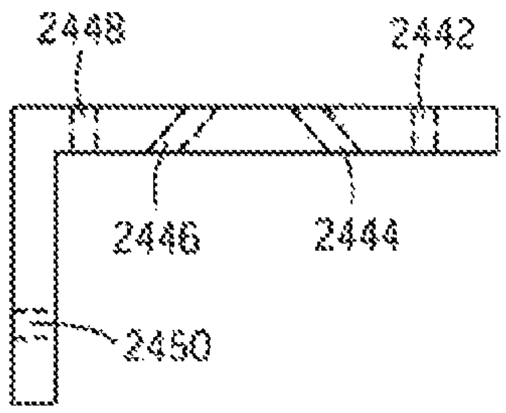


FIG. 16G

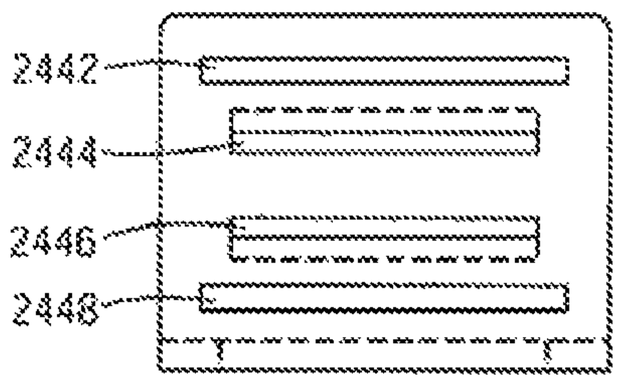


FIG. 16H

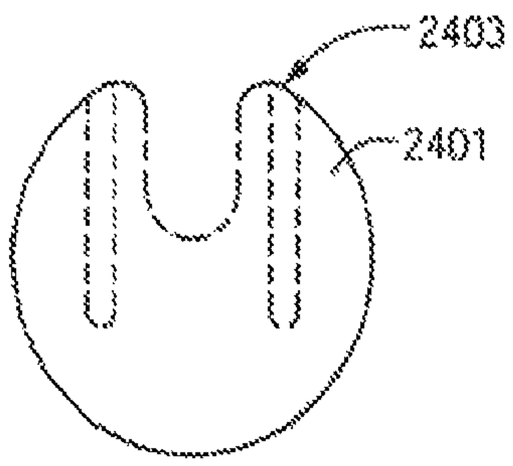


FIG. 16I

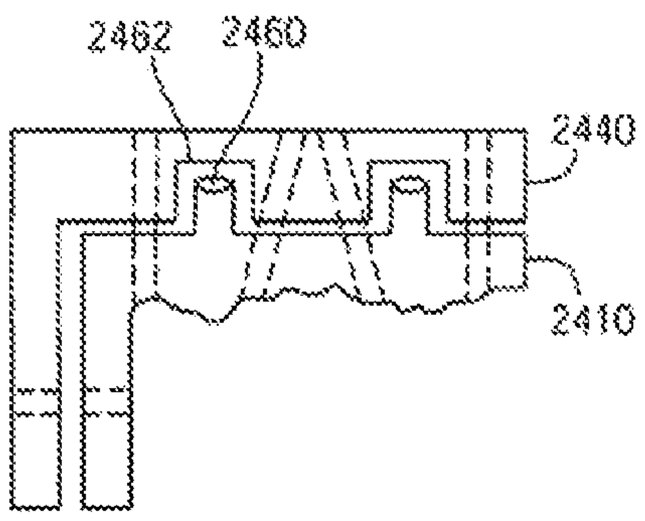


FIG. 16J

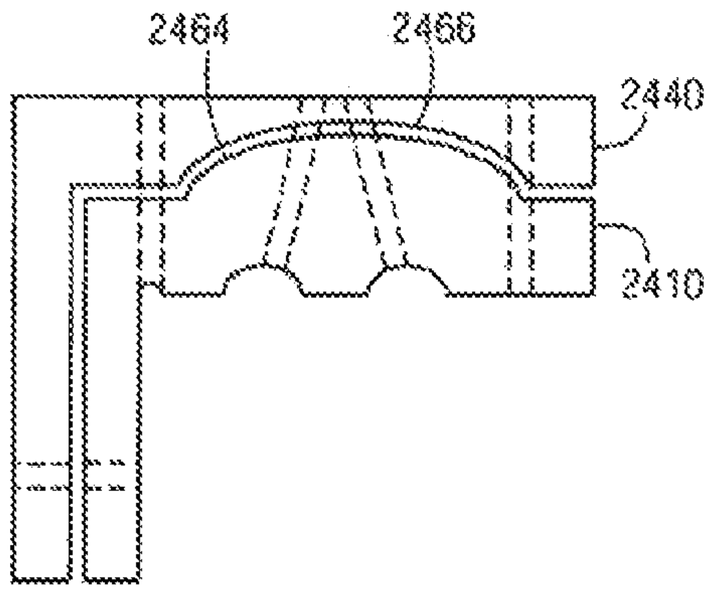


FIG. 16K

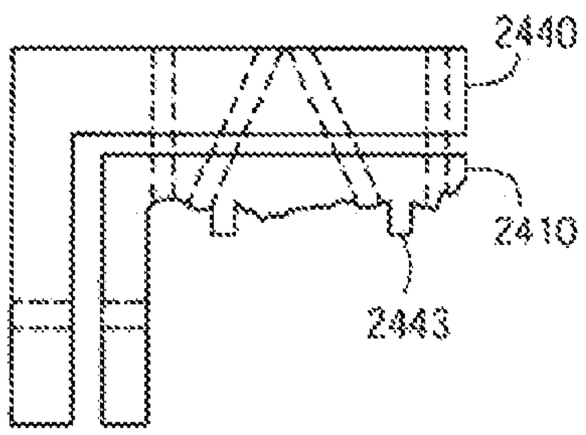


FIG. 16L

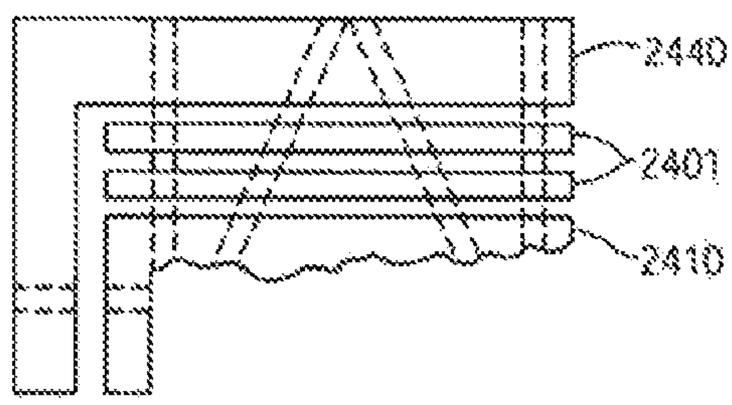


FIG. 16M

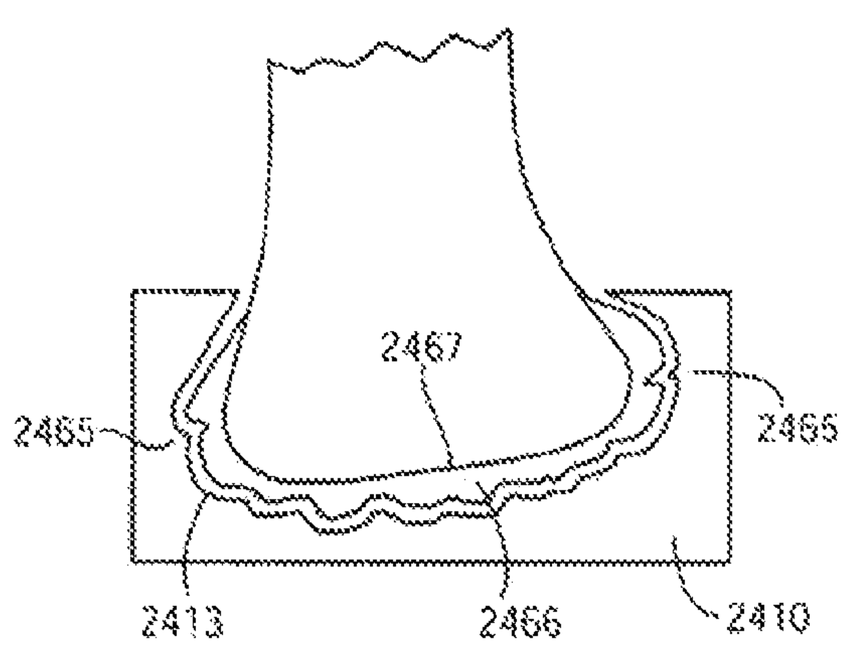


FIG. 16N

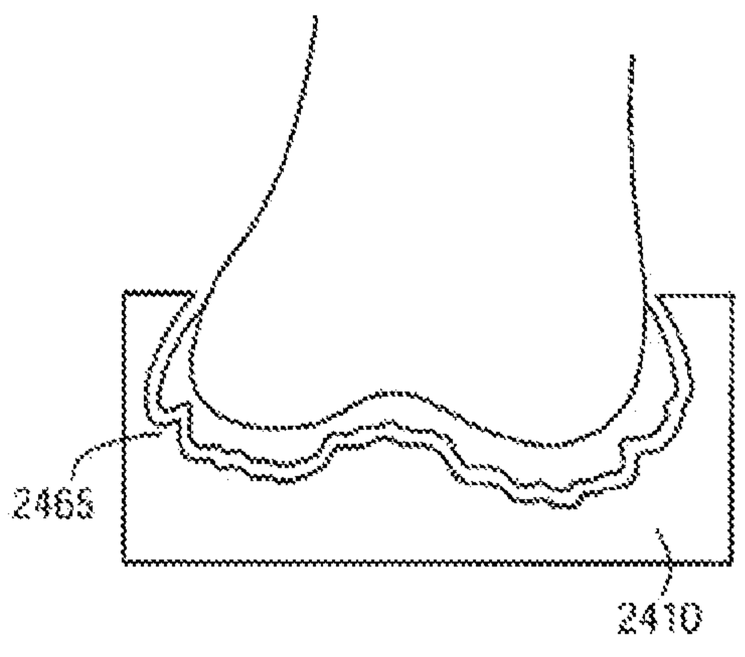
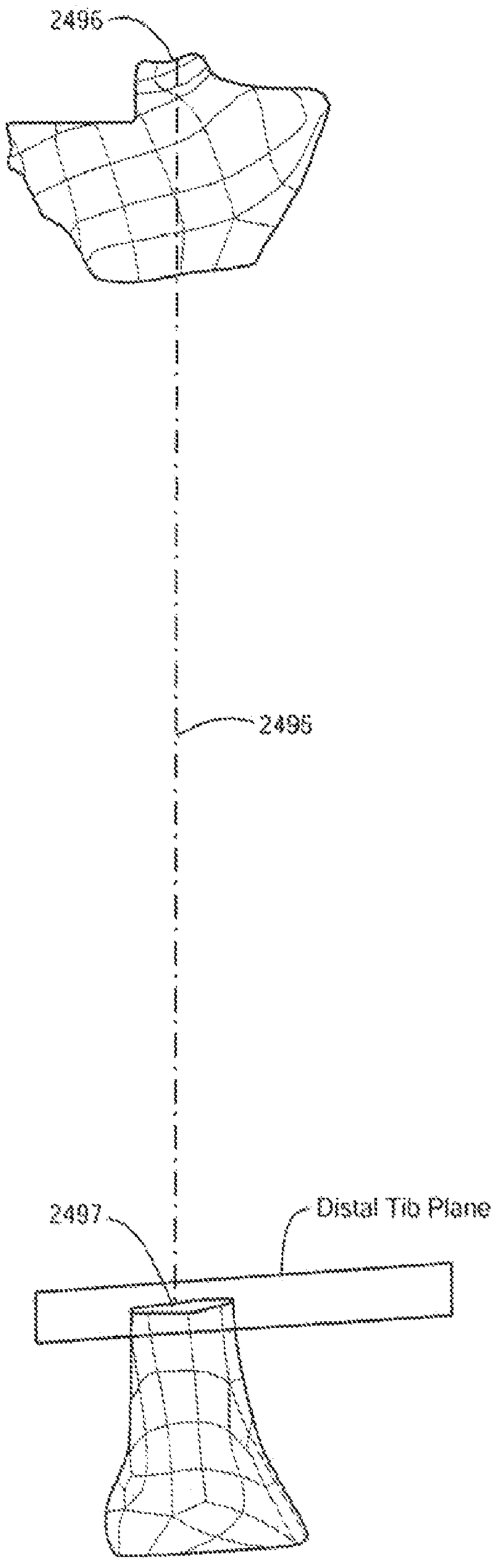


FIG. 16O

FIG. 16P



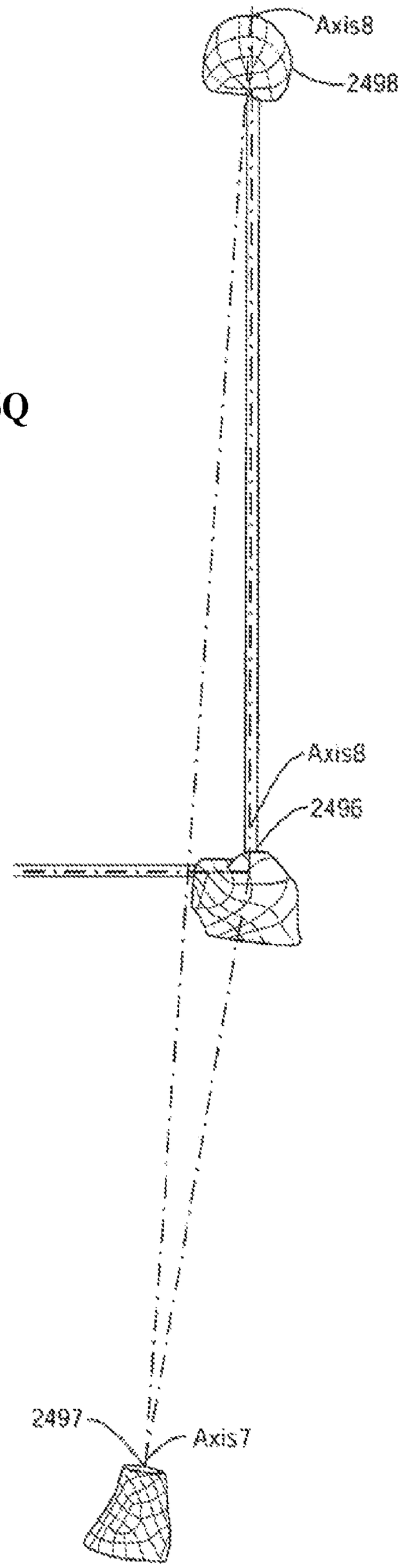


FIG. 16Q

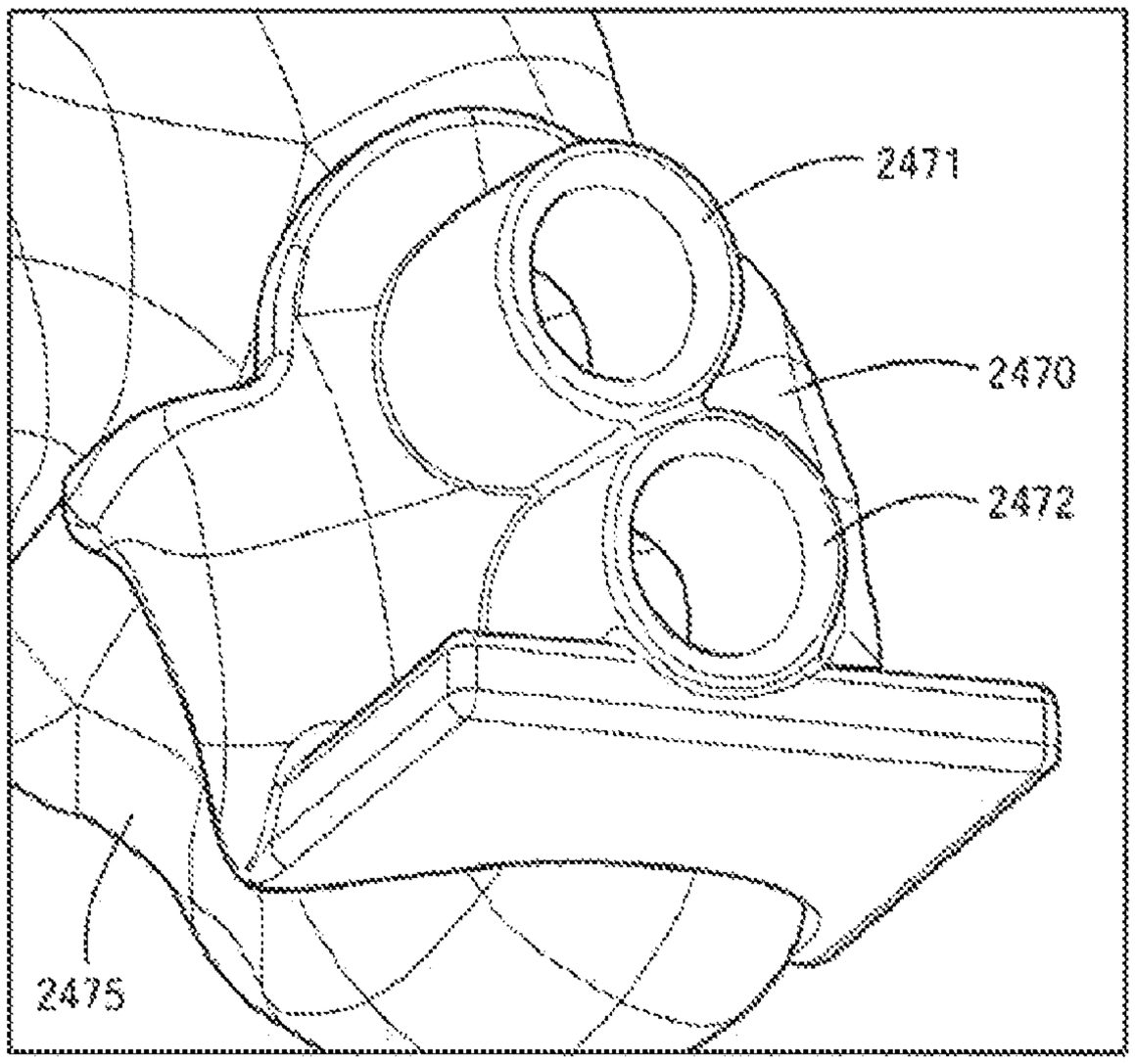


FIG. 16R

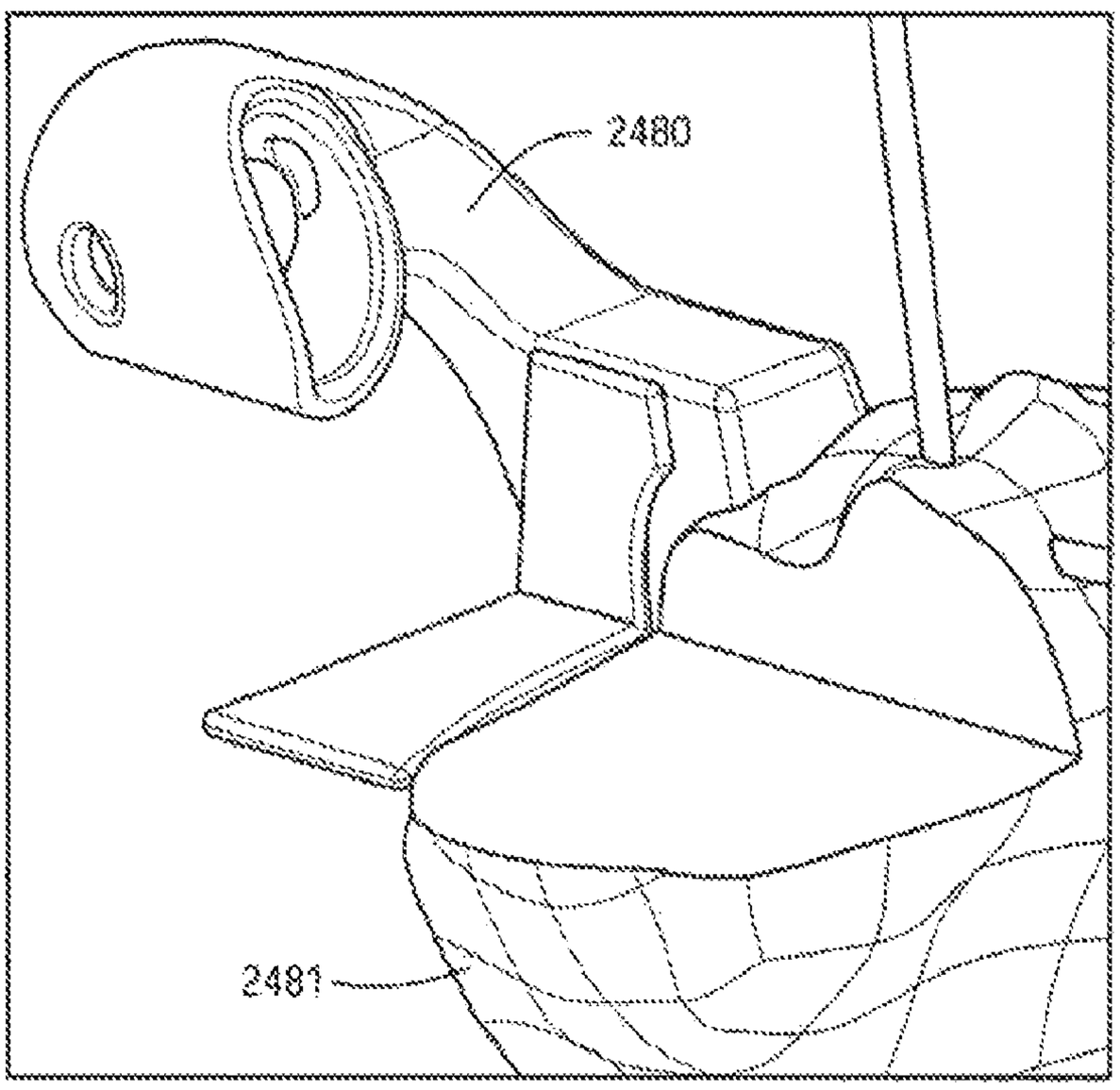


FIG. 16S

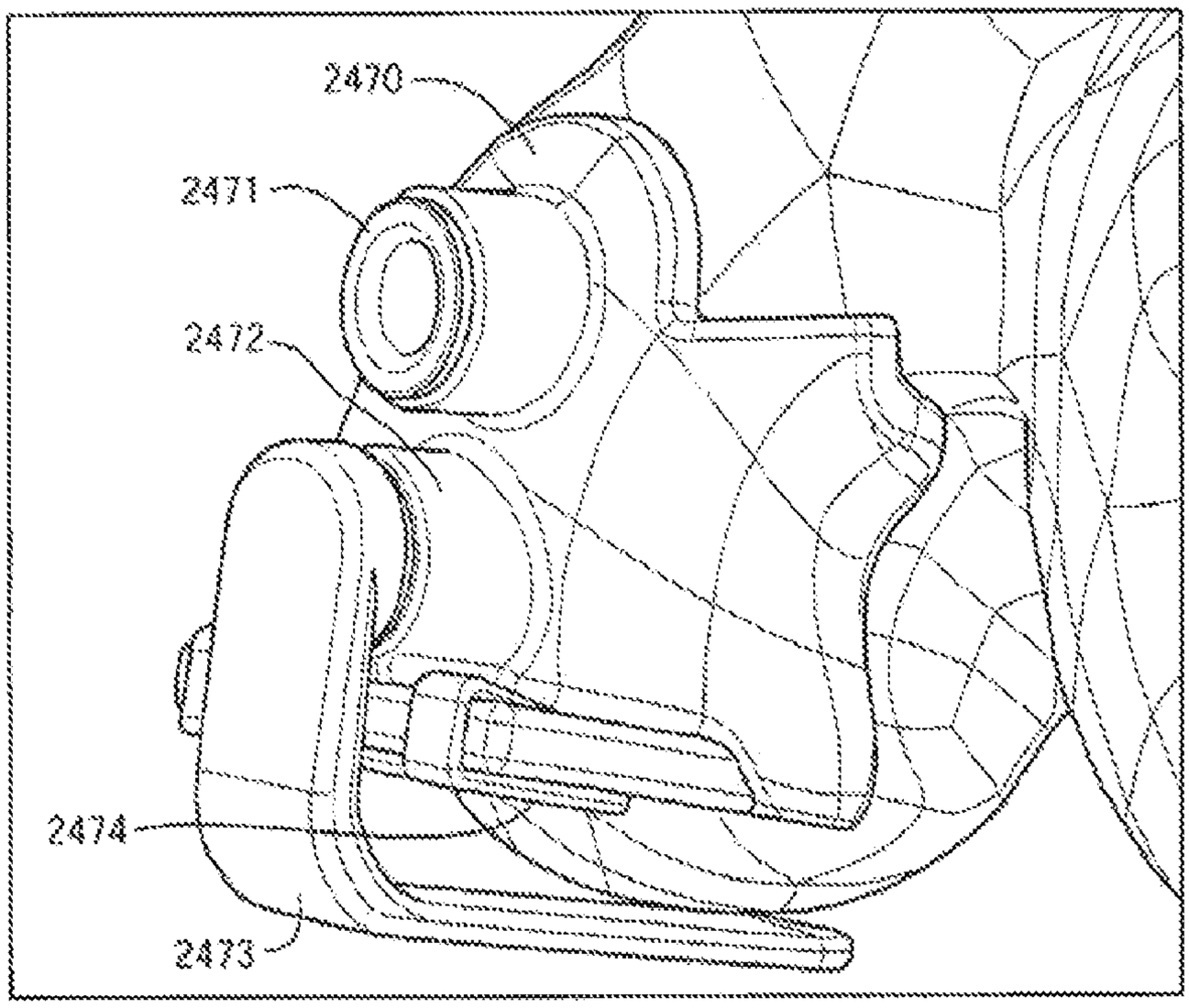


FIG. 16T

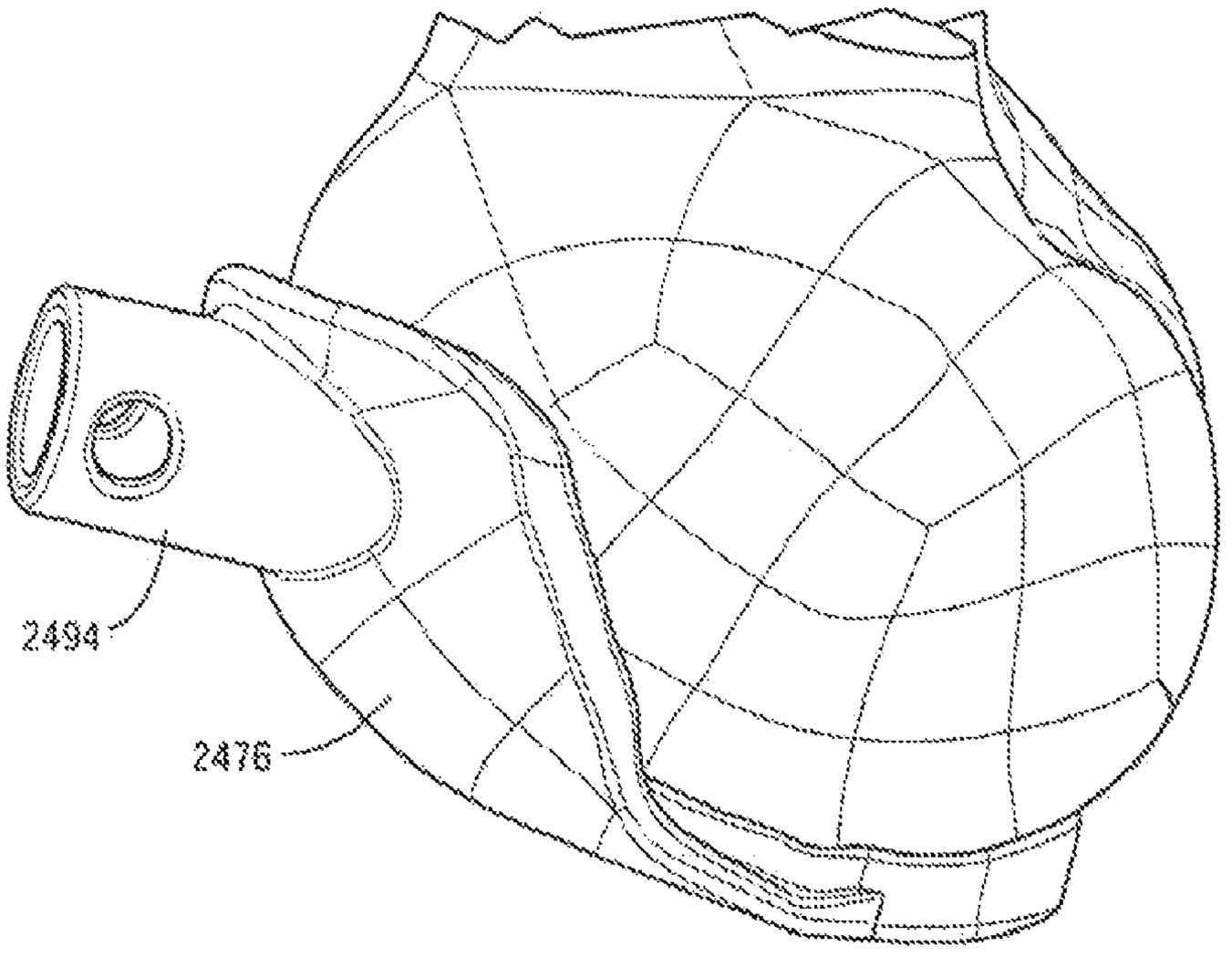


FIG 16U

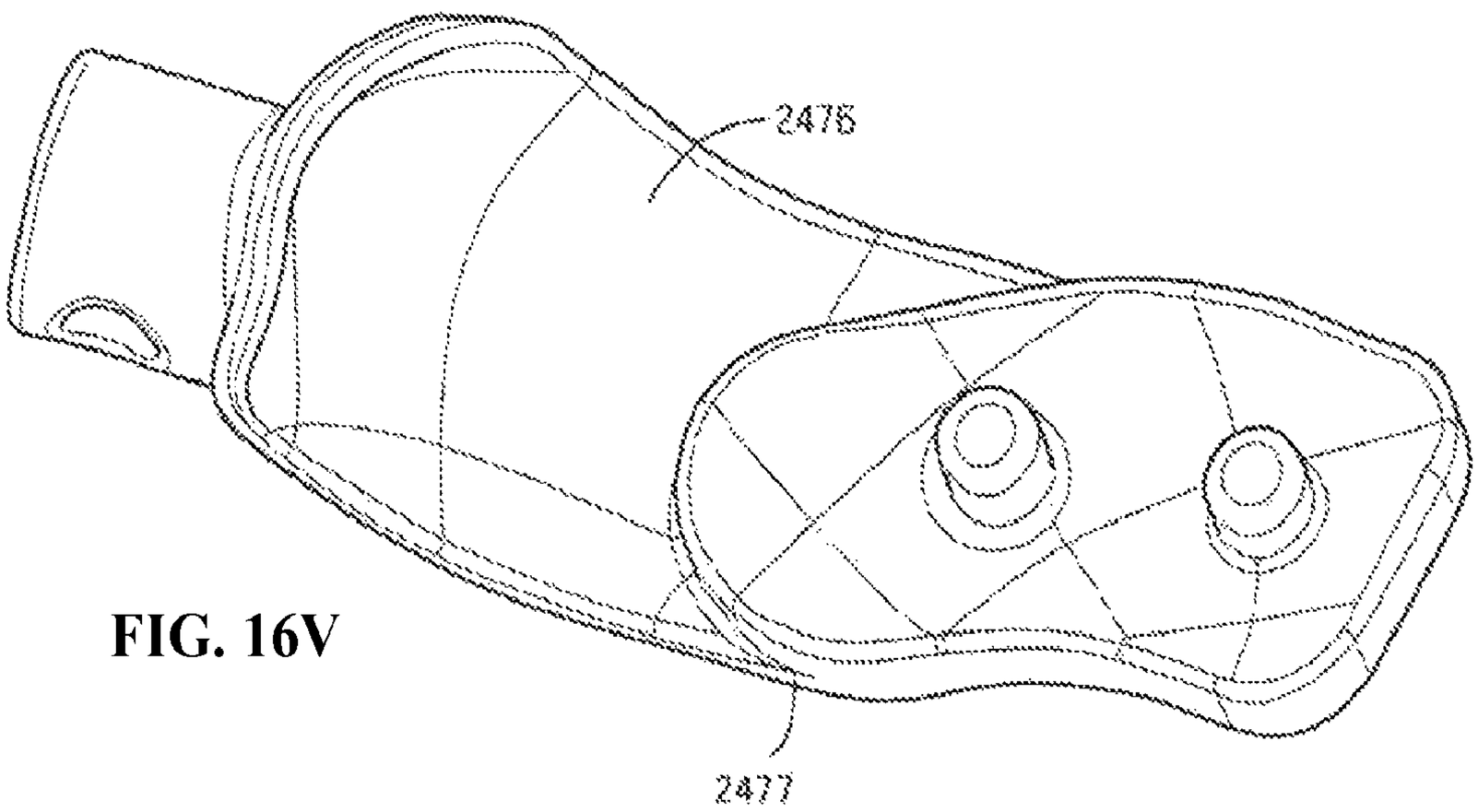


FIG. 16V

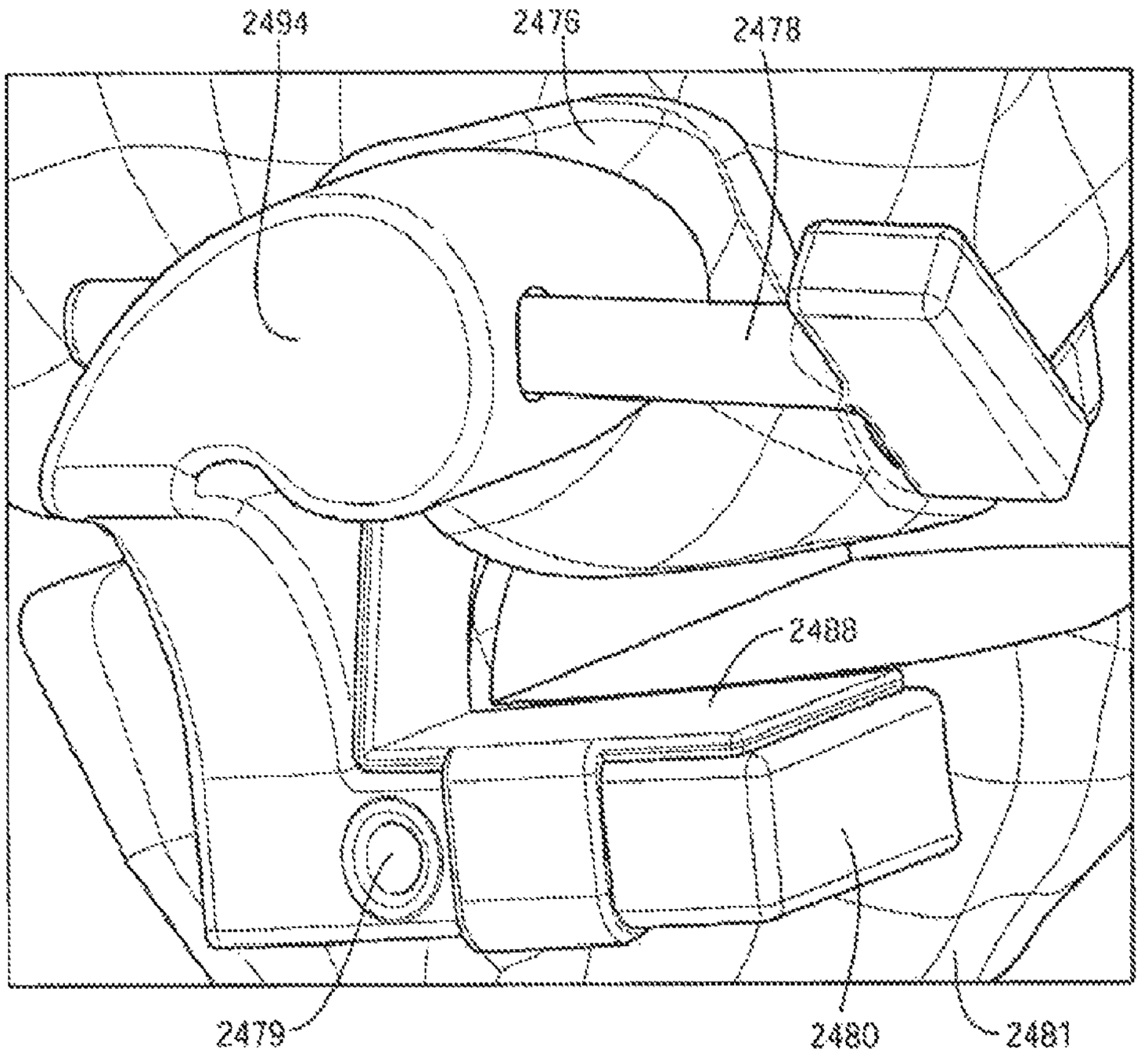


FIG. 16W

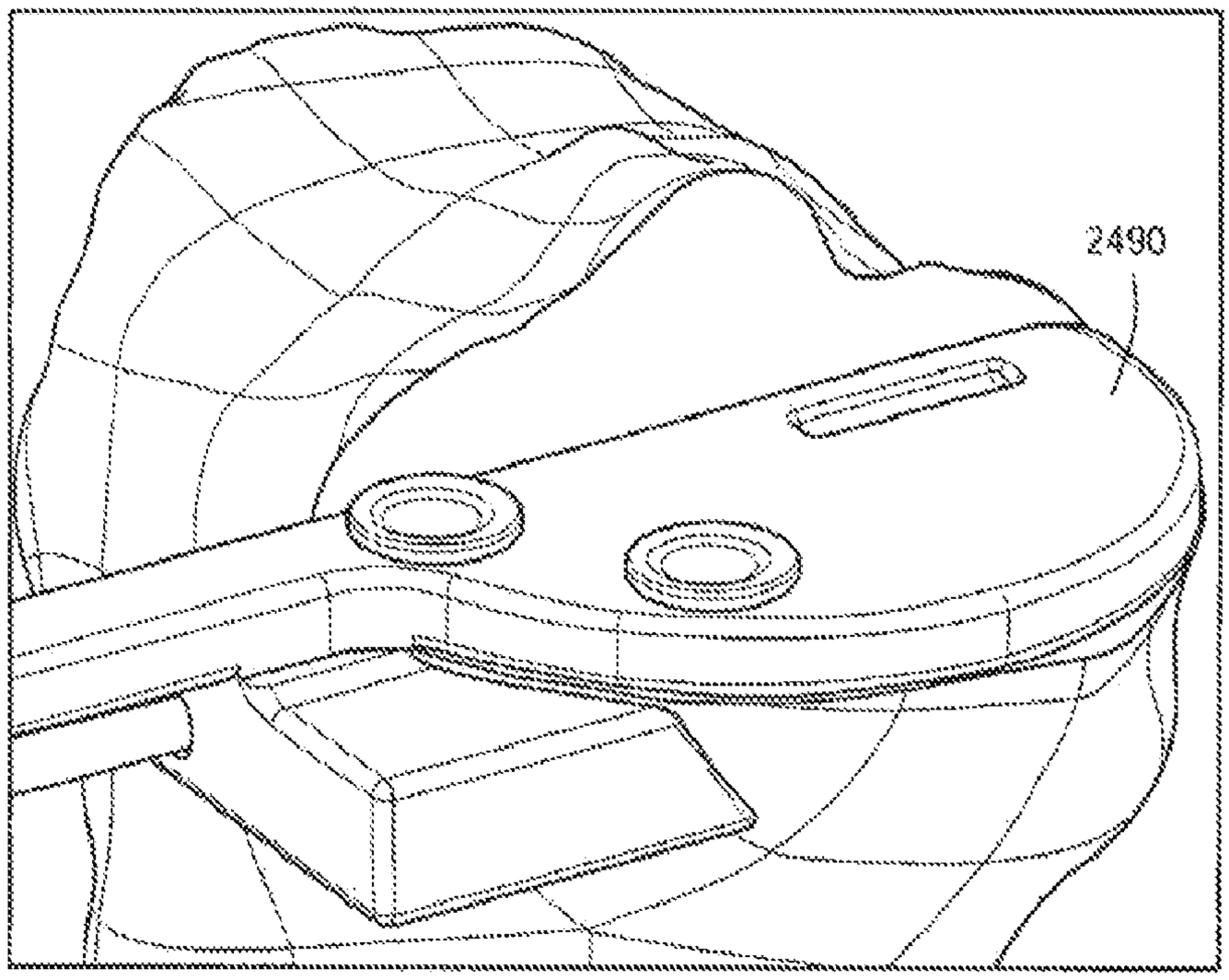


FIG. 16X

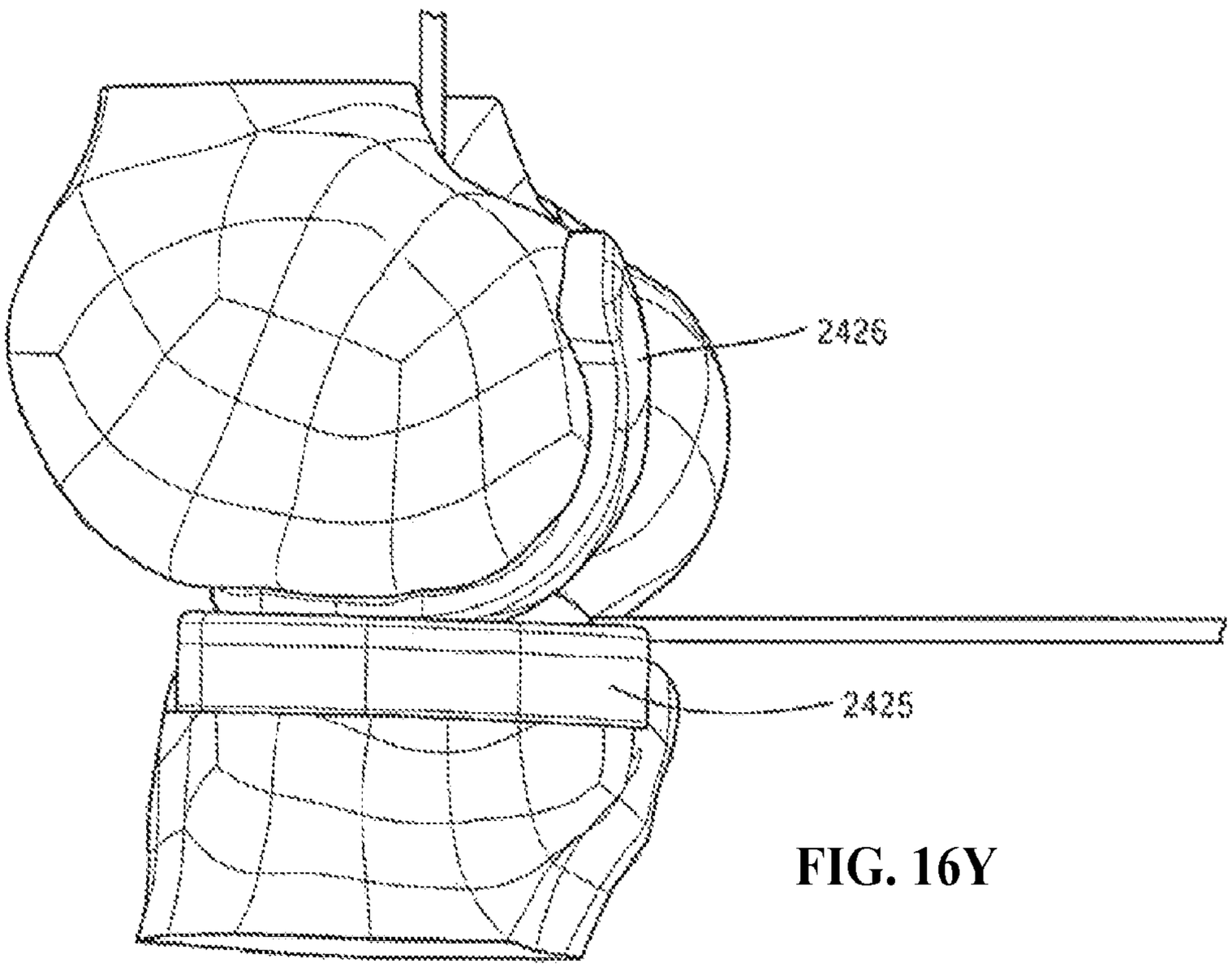


FIG. 16Y

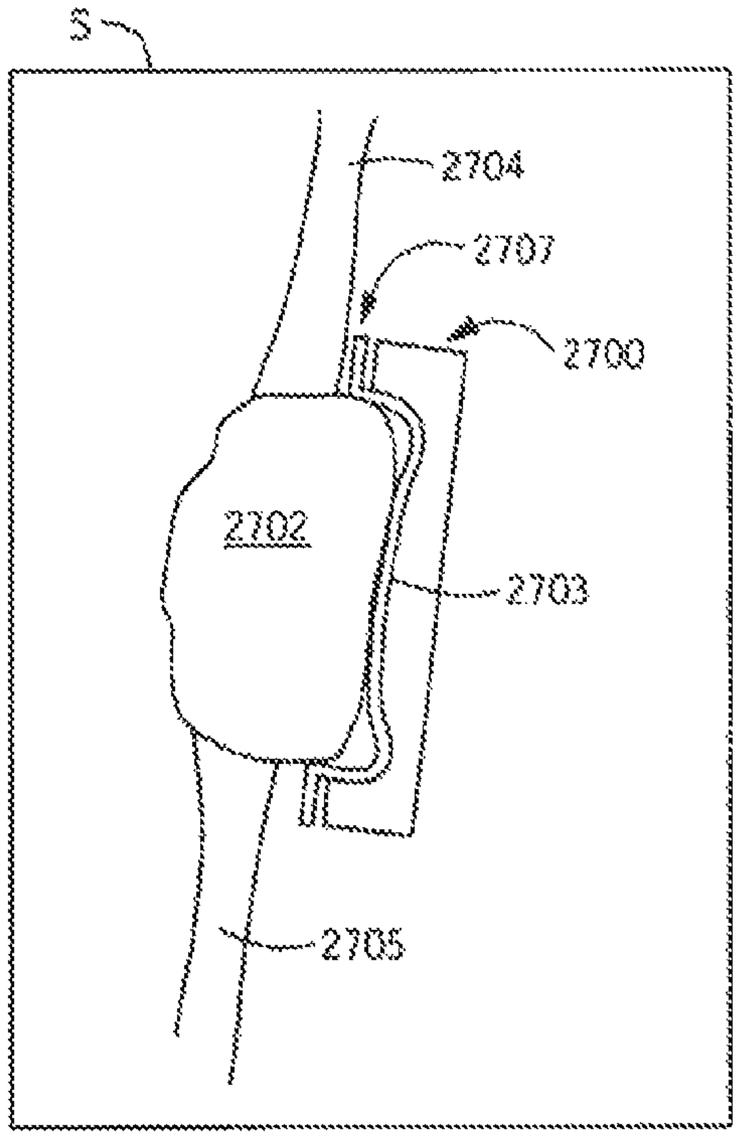


FIG 17A

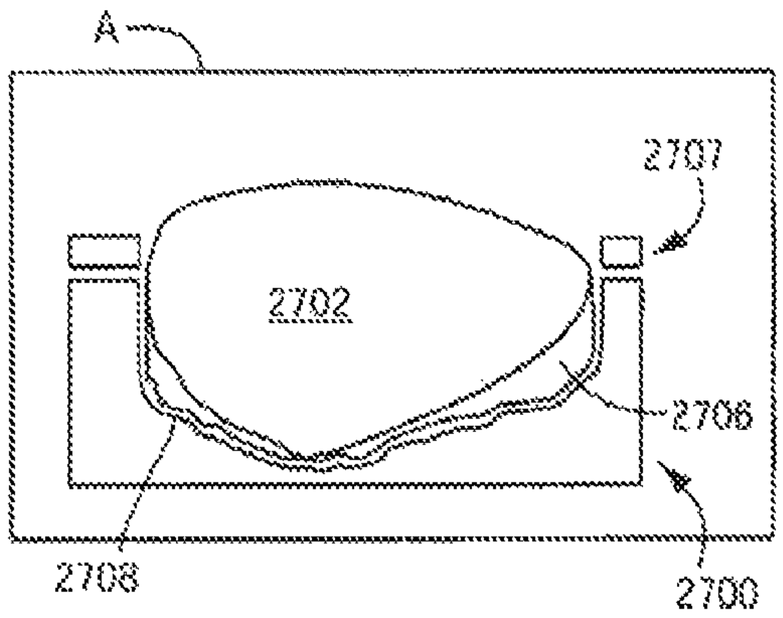


FIG. 17B

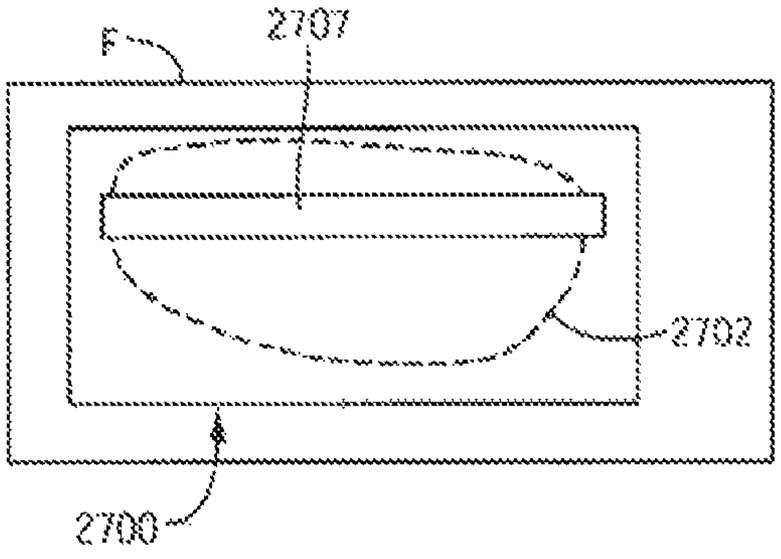


FIG. 17C

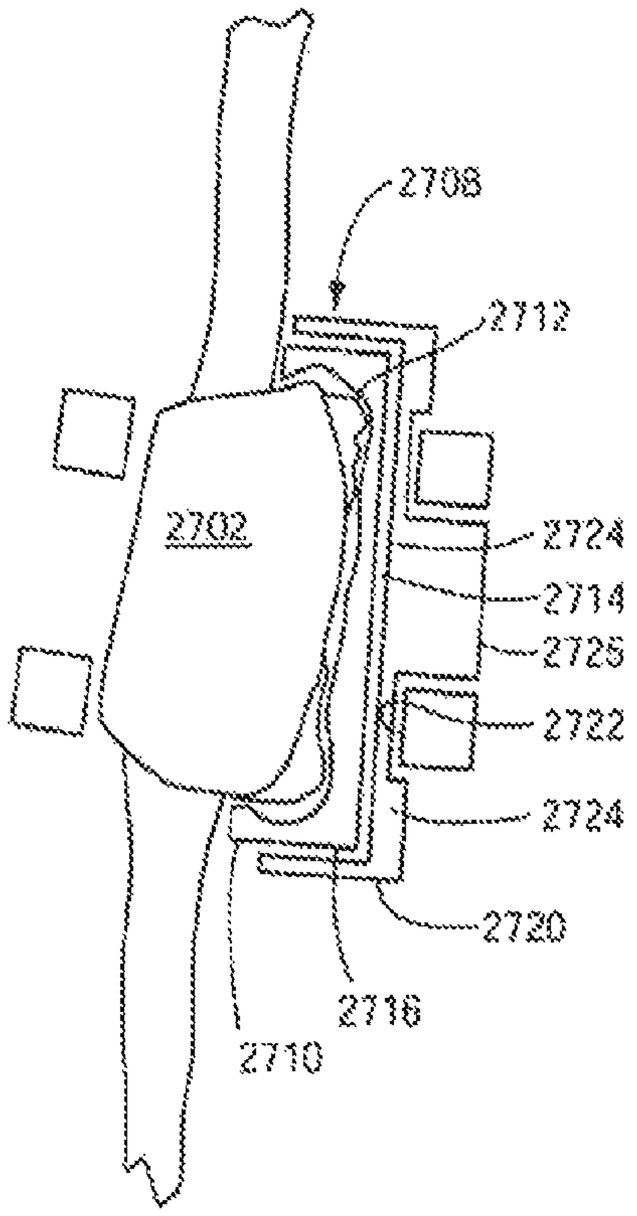


FIG. 17D

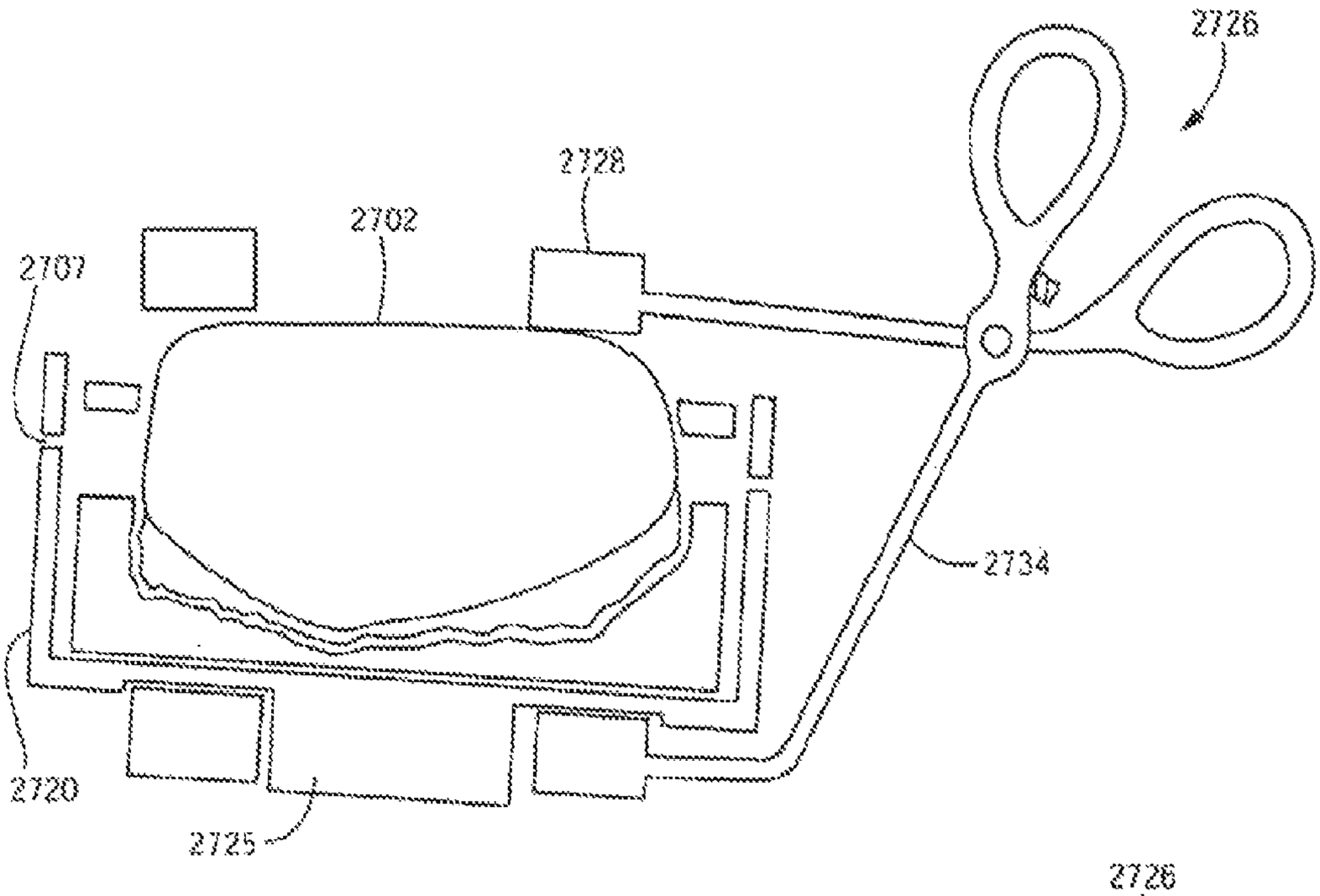


FIG. 17E

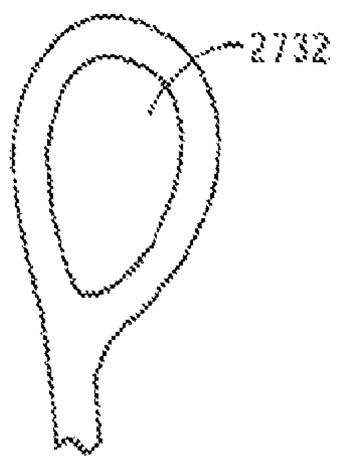


FIG. 17F

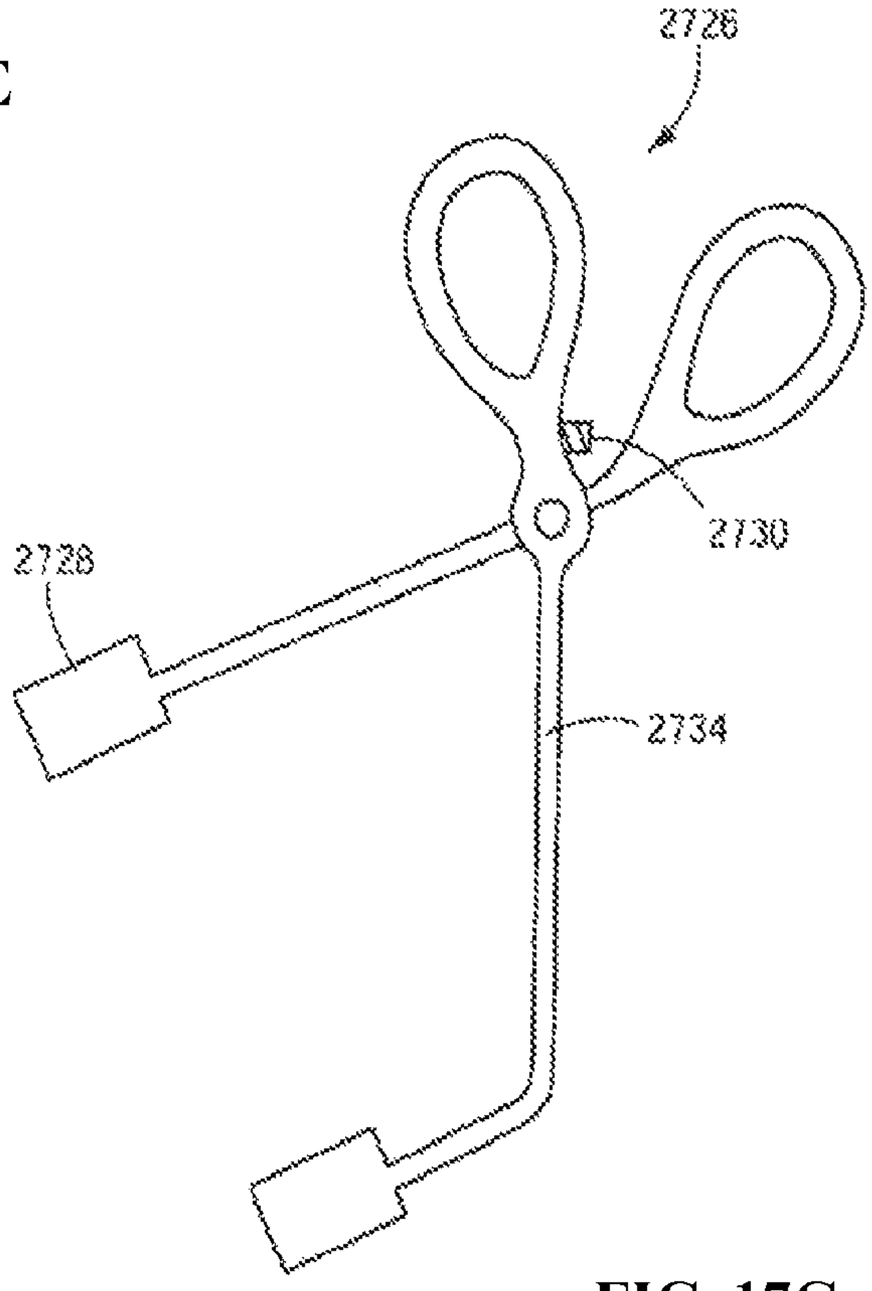


FIG. 17G

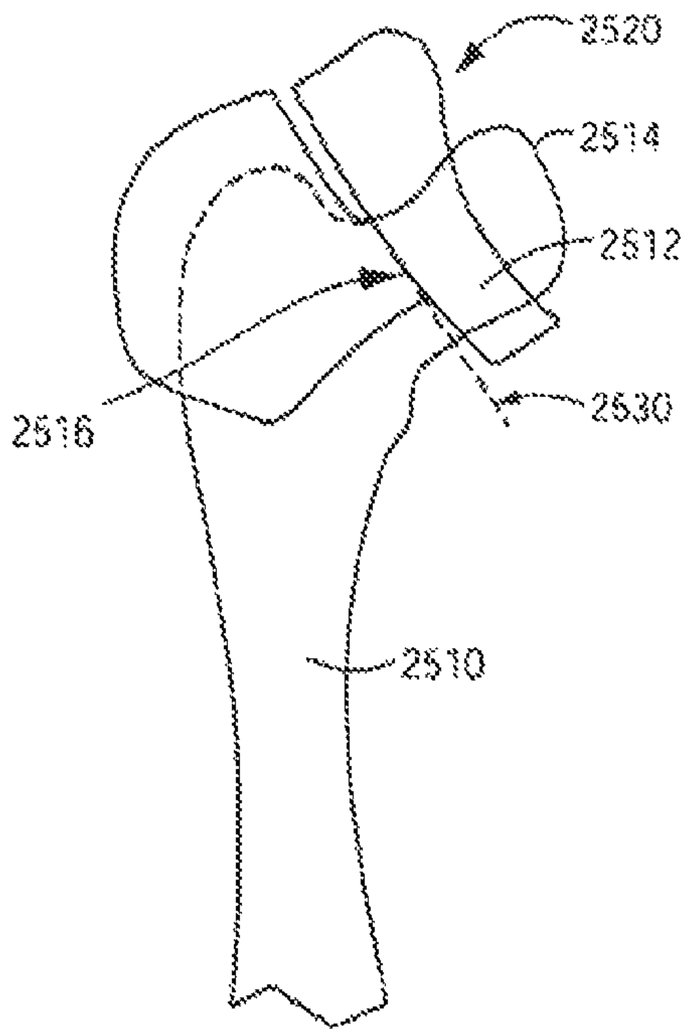


FIG. 18A

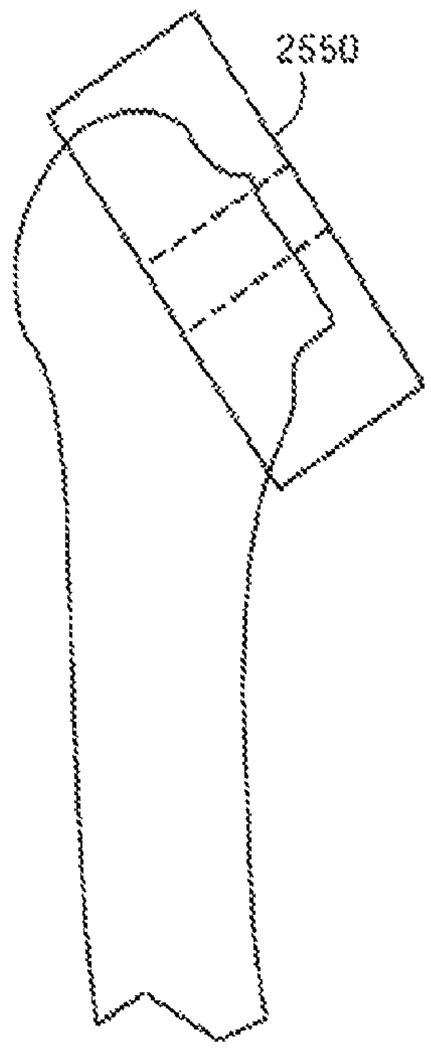


FIG. 18C

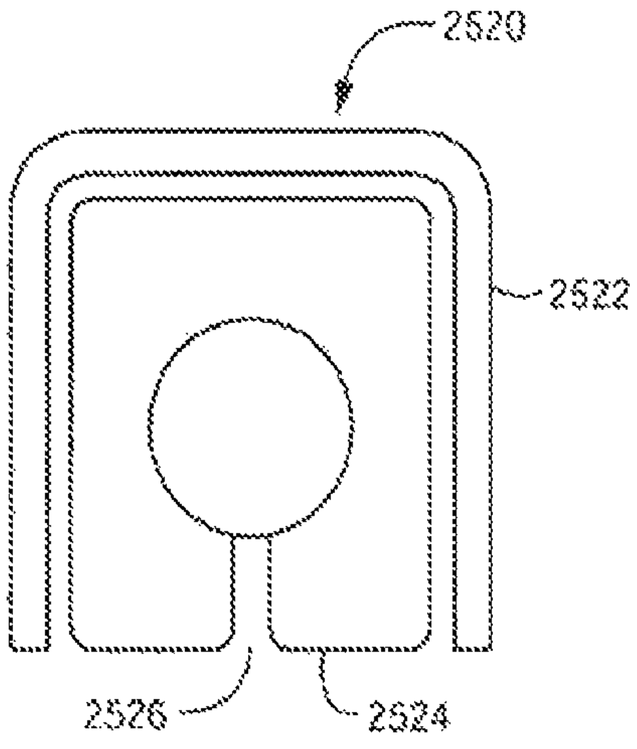


FIG. 18B

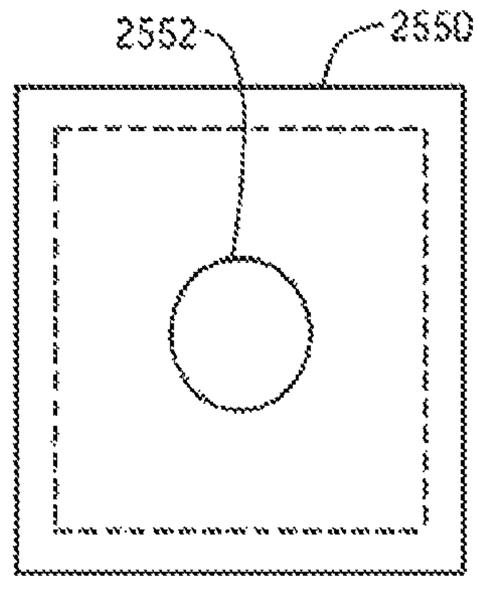


FIG. 18D

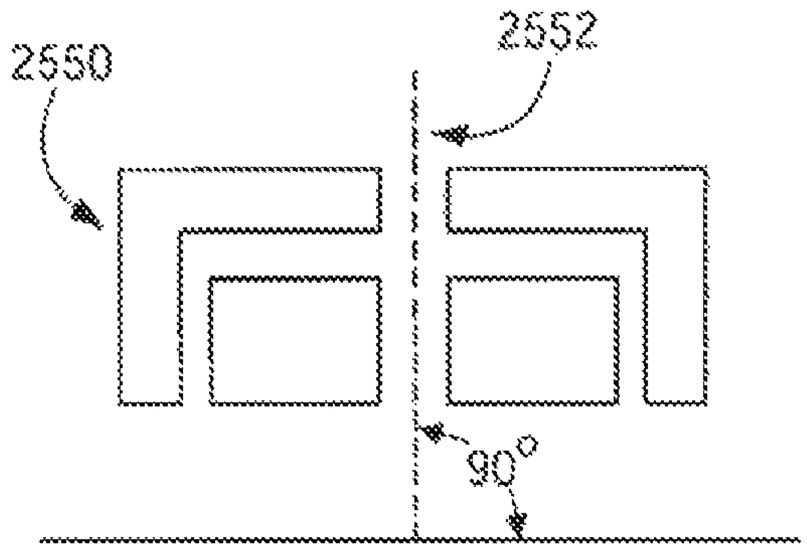


FIG. 18E

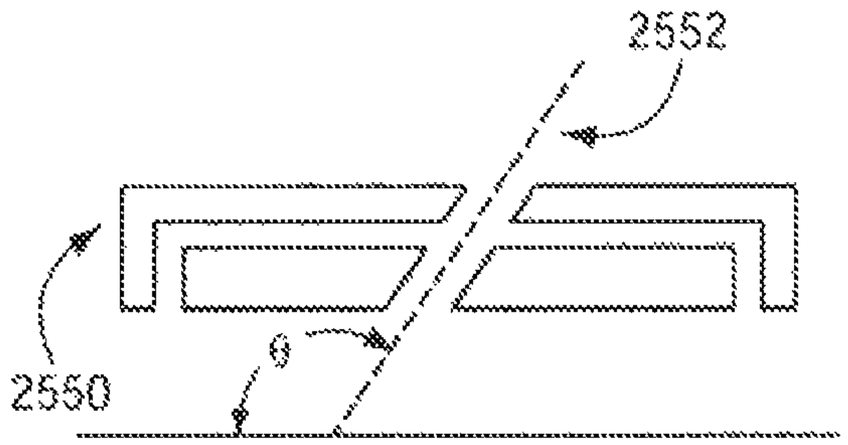


FIG. 18F

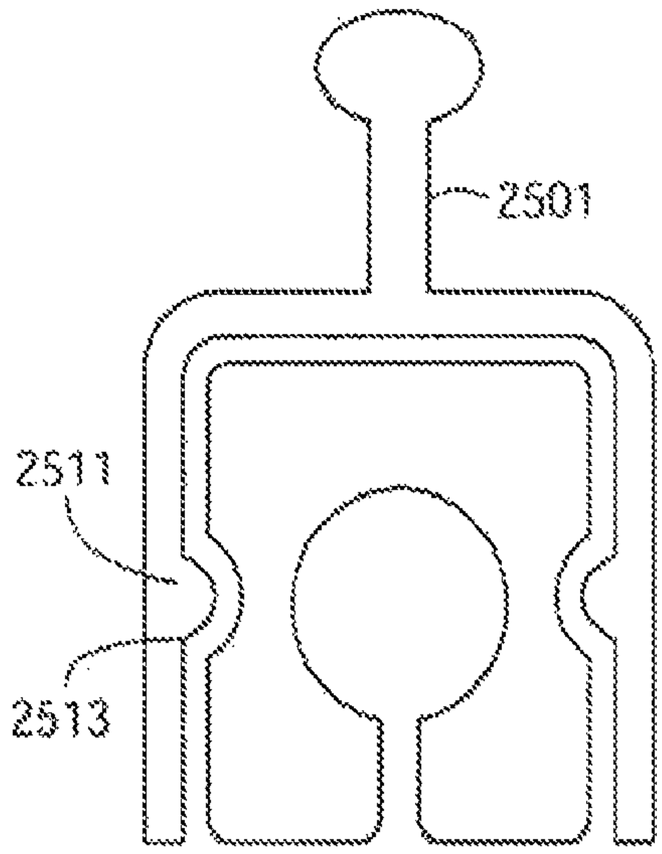


FIG. 18G

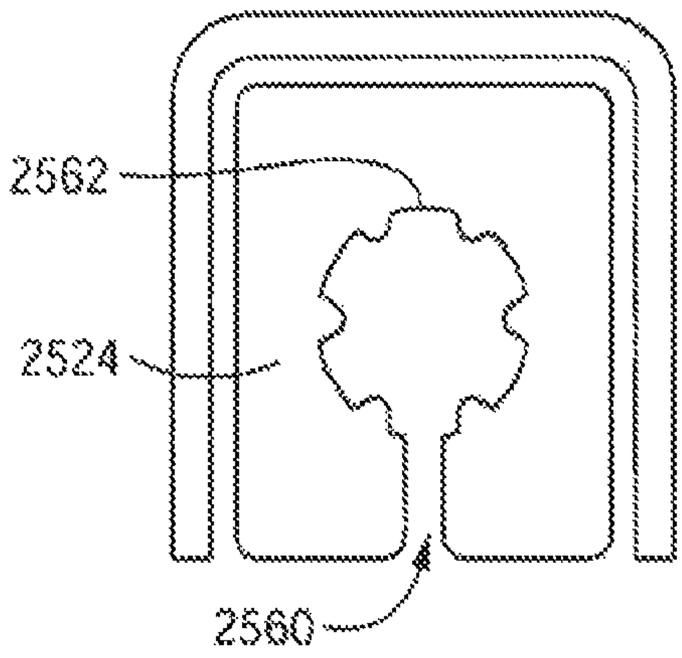


FIG. 18H

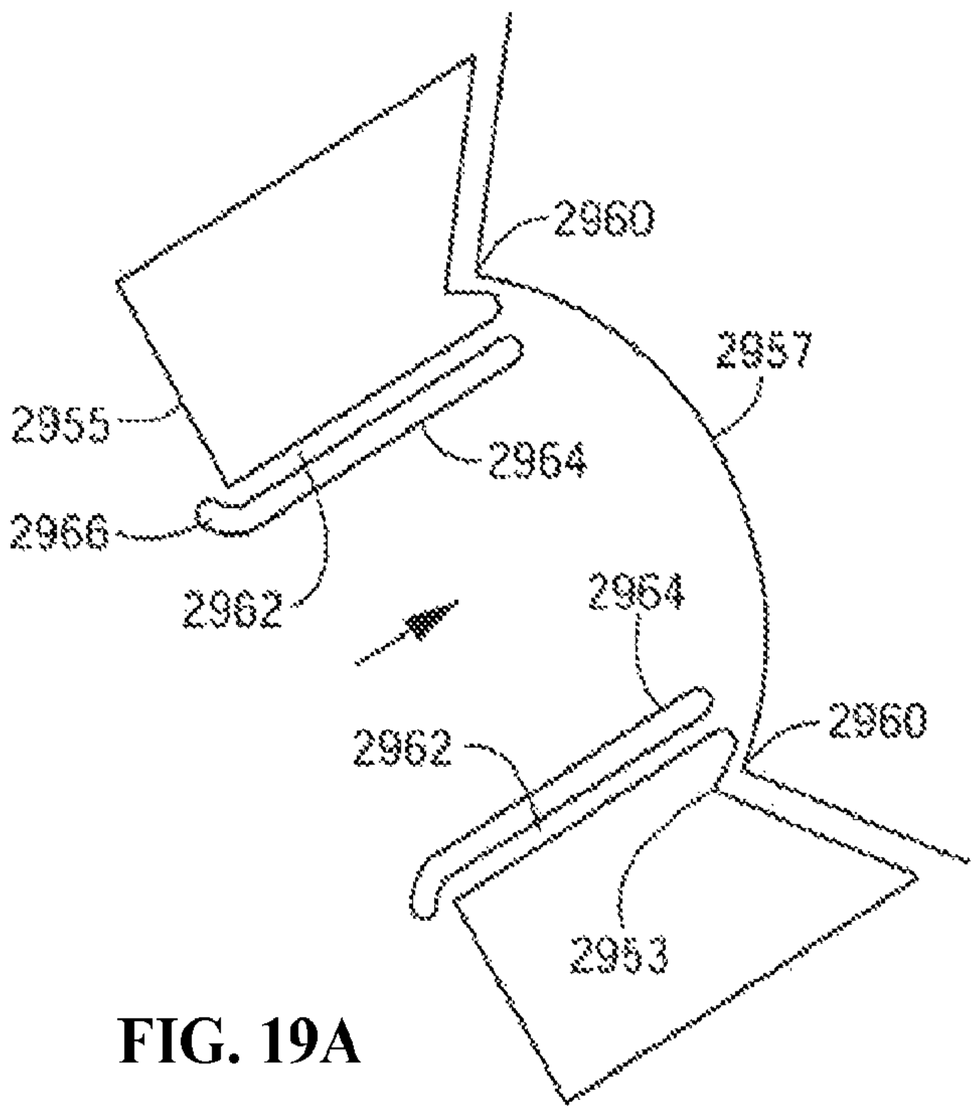


FIG. 19A

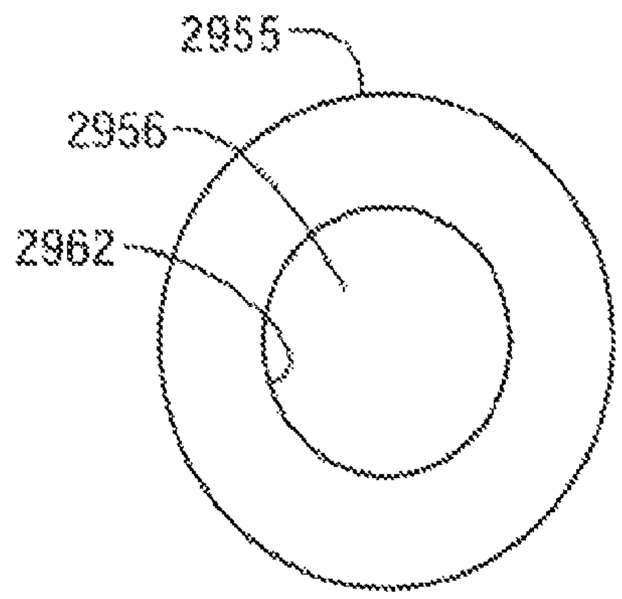


FIG. 19B

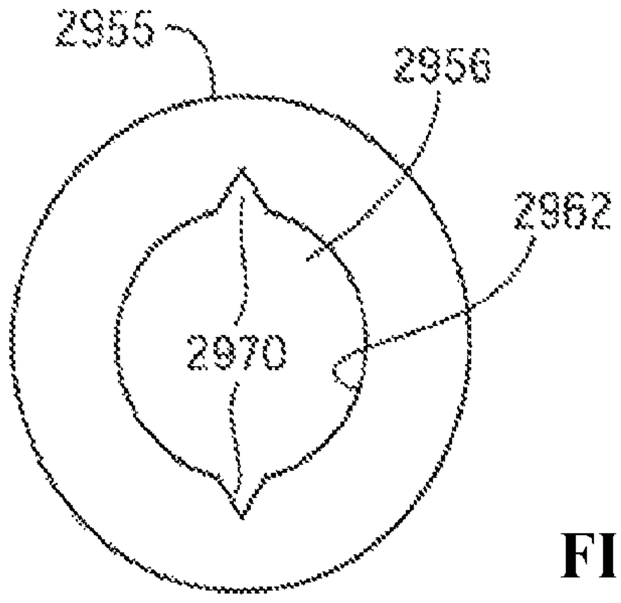


FIG. 19C

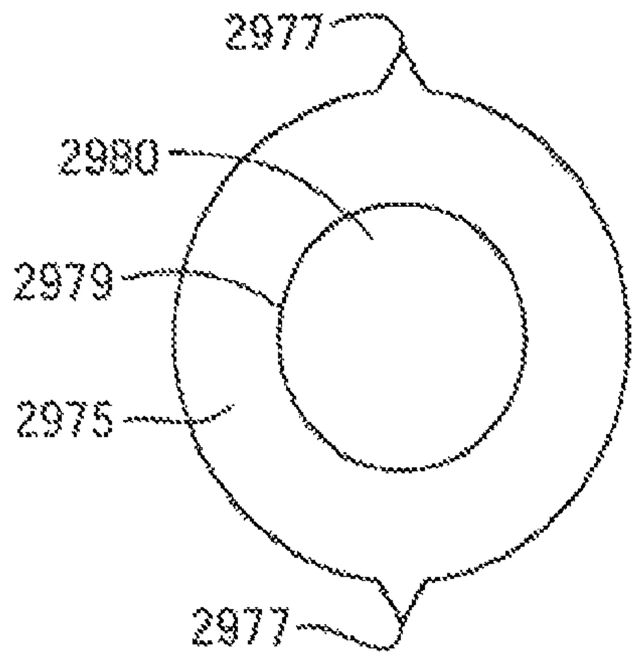


FIG. 19D

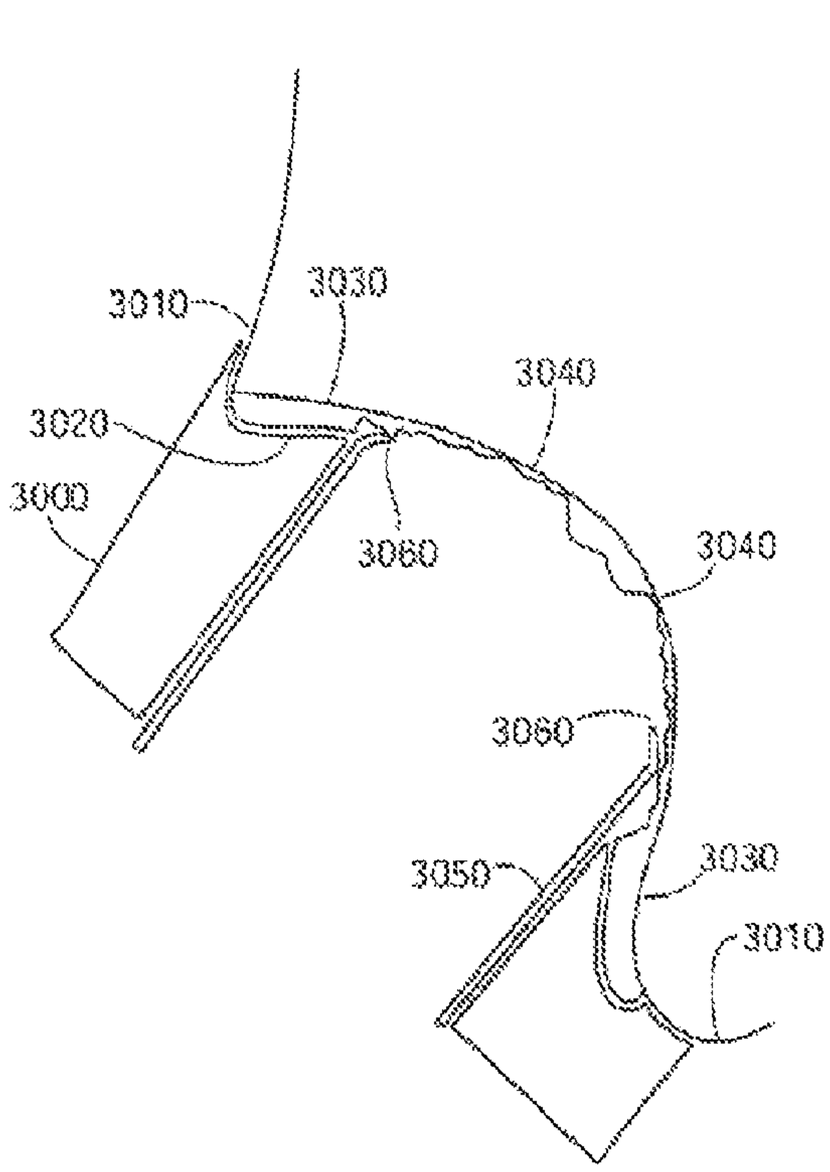

3010
3030
3040
3020
3000
3060
3040
3060
3050
3030
3010

FIG. 20

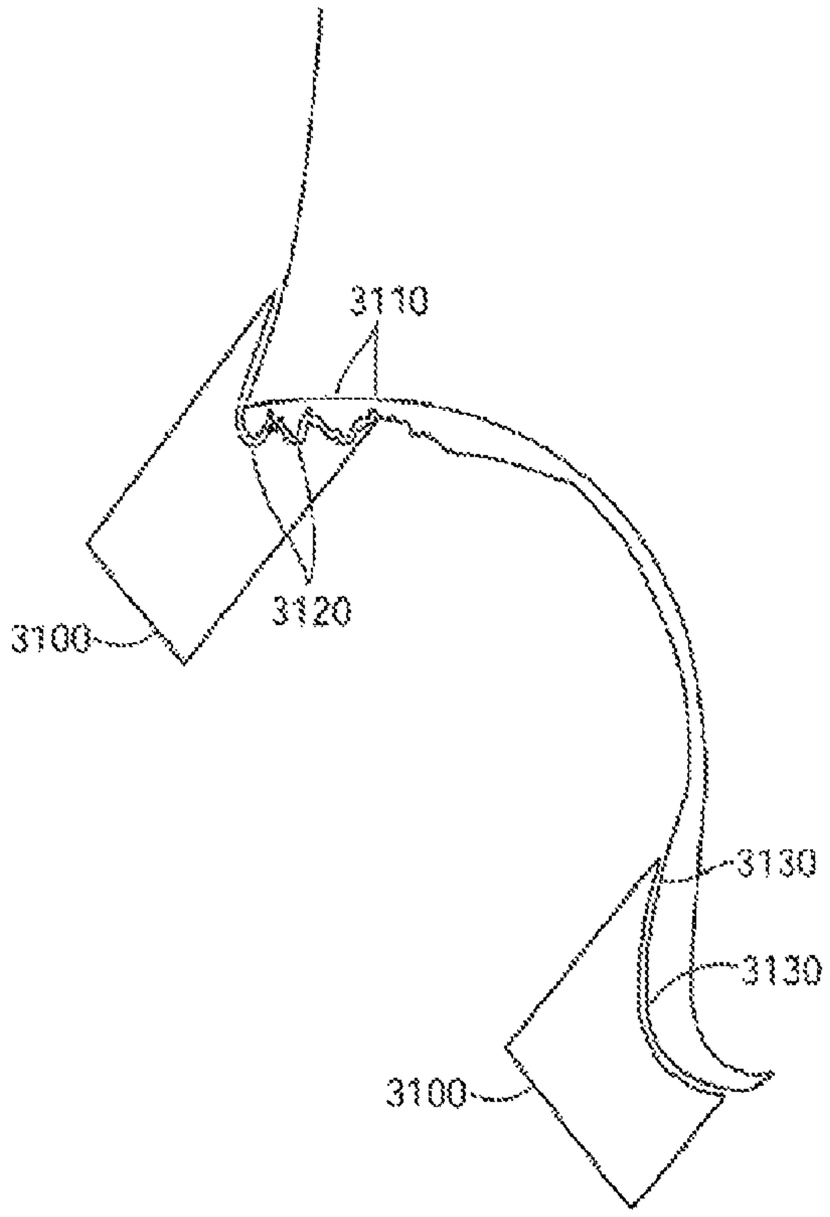

3110
3100
3120
3130
3130
3100

FIG. 21

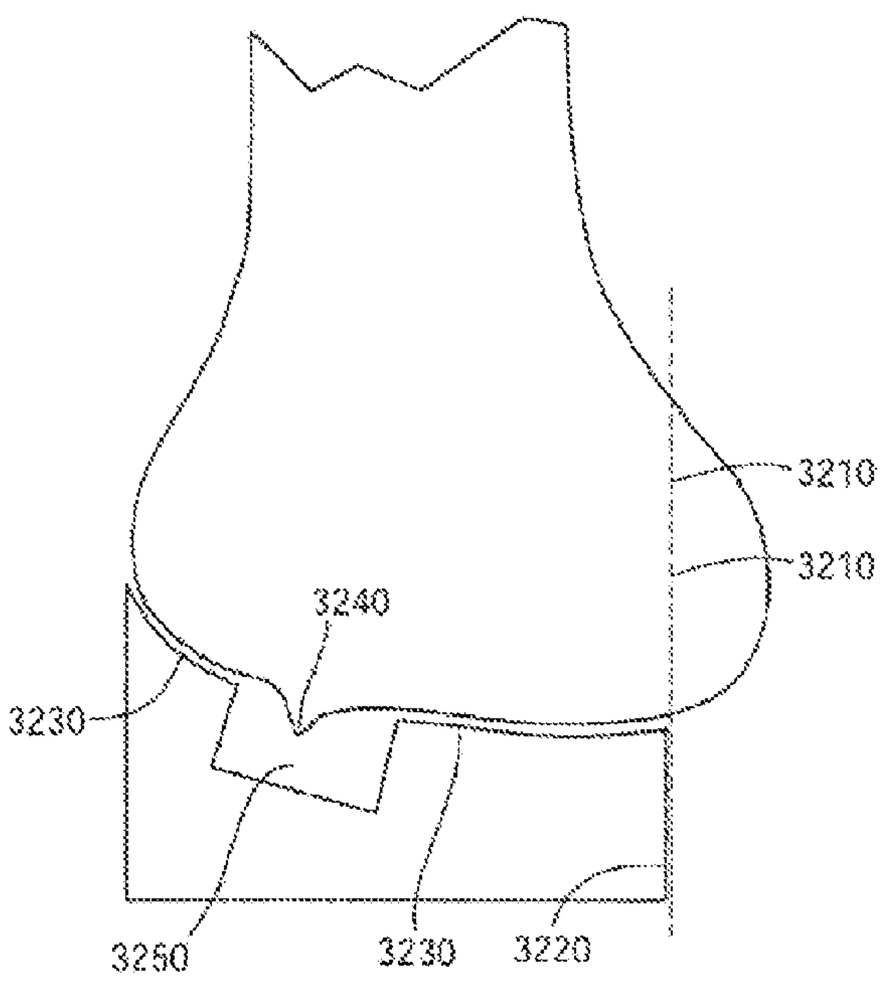


FIG. 22

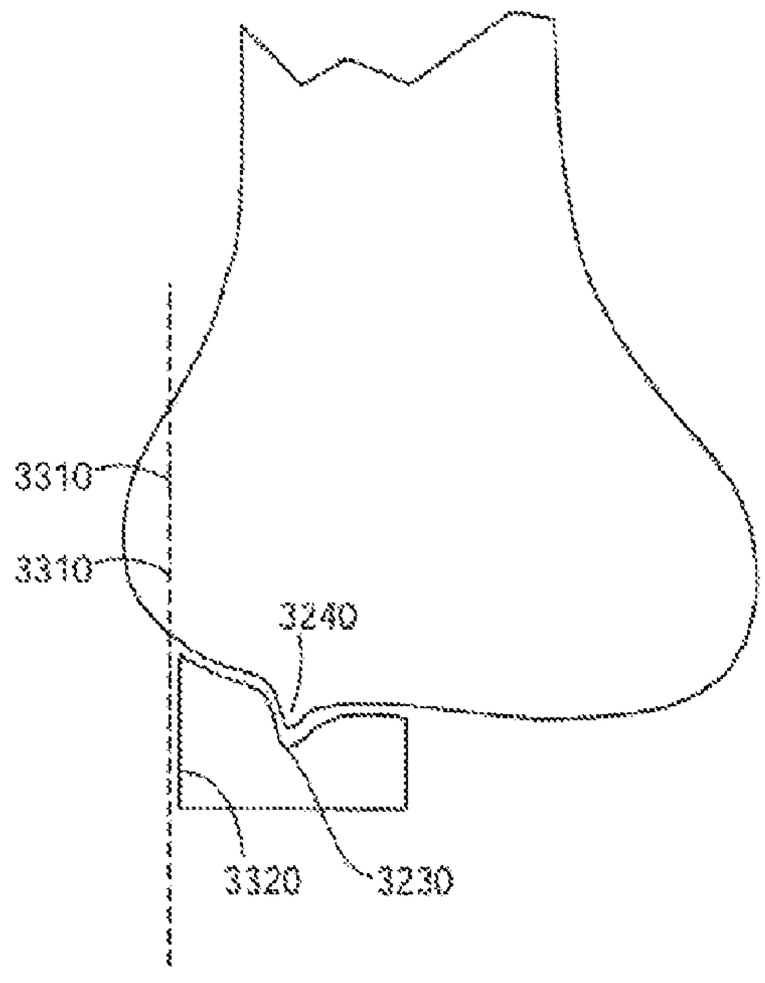


FIG. 23

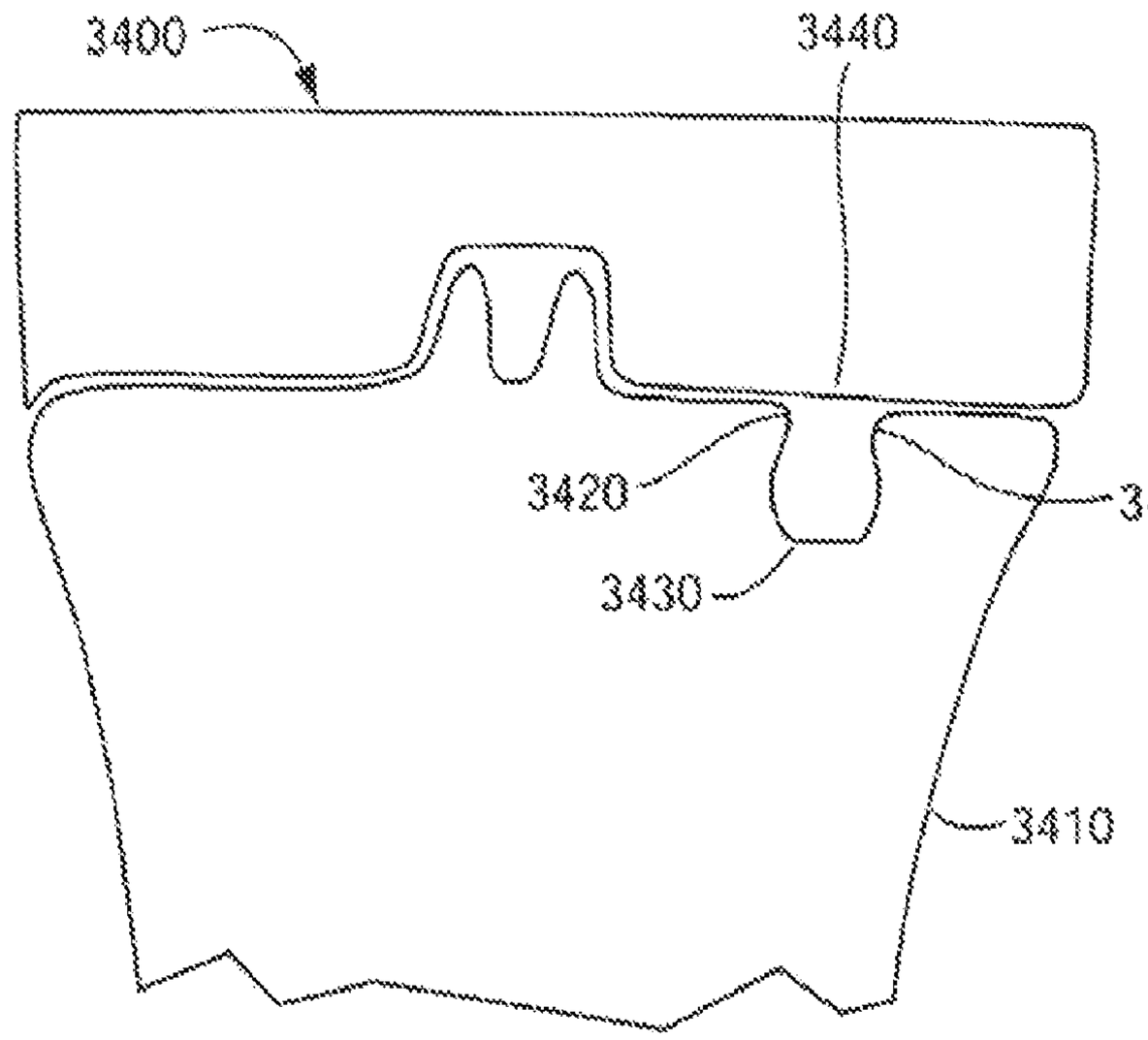
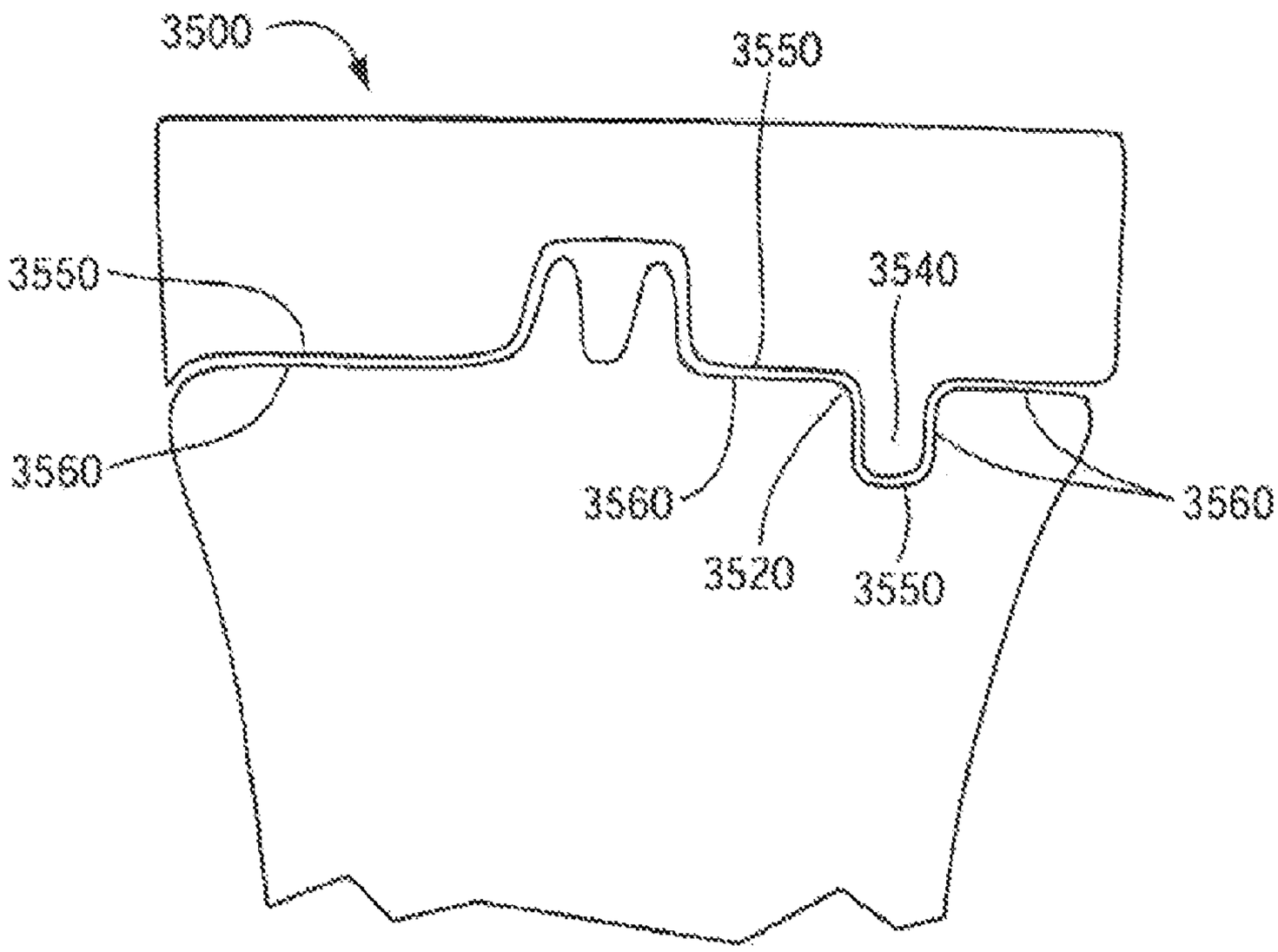

3400
3440
3420
3420
3430
3410

FIG. 24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3550
3550
3540
3560
3560
3560
3520
3550

FIG. 25

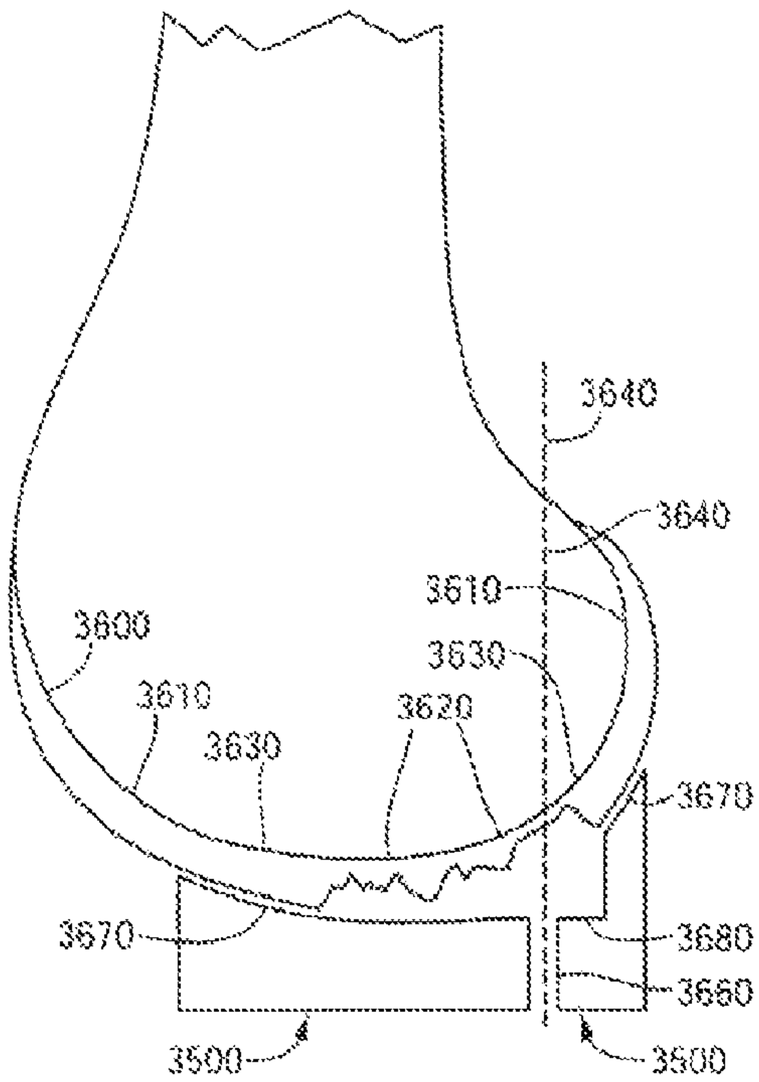

FIG. 26A

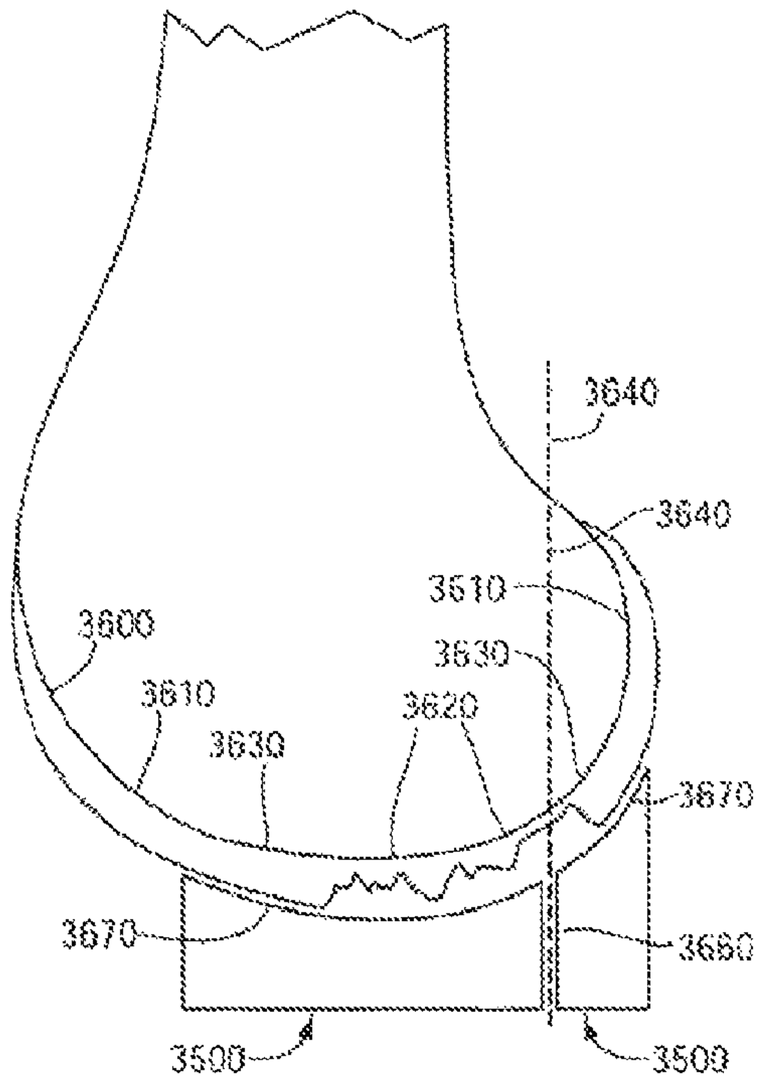

FIG. 26B

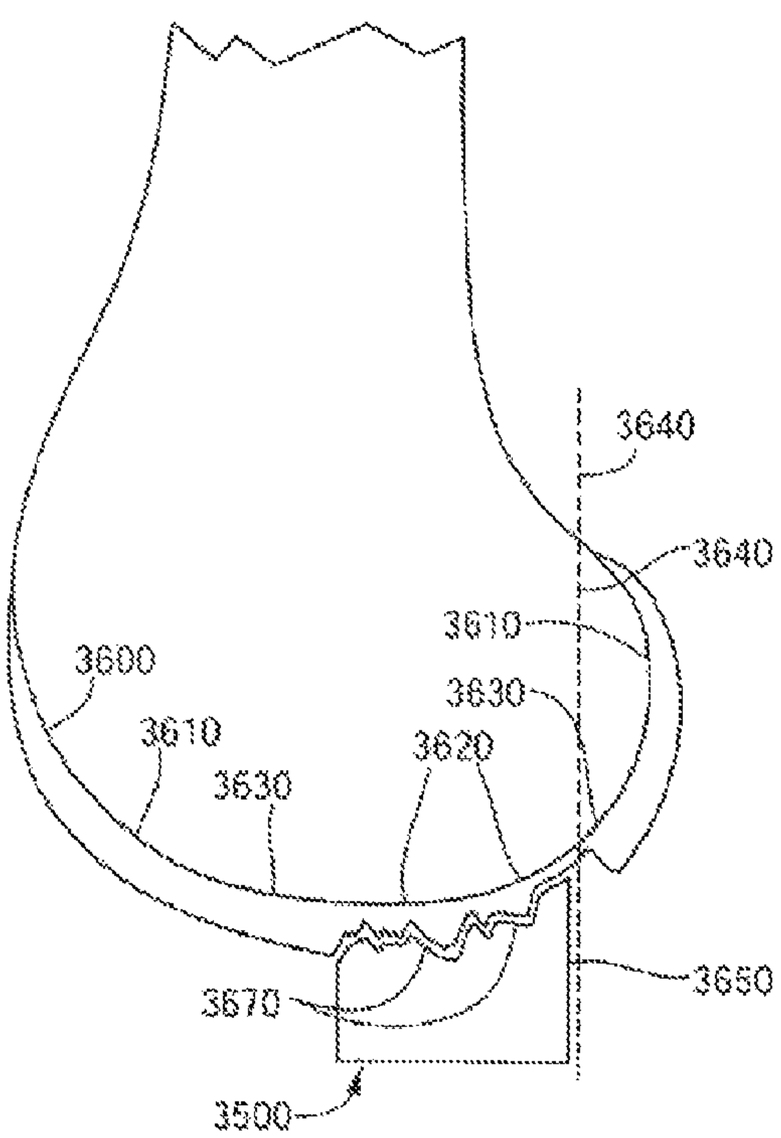

FIG. 26C

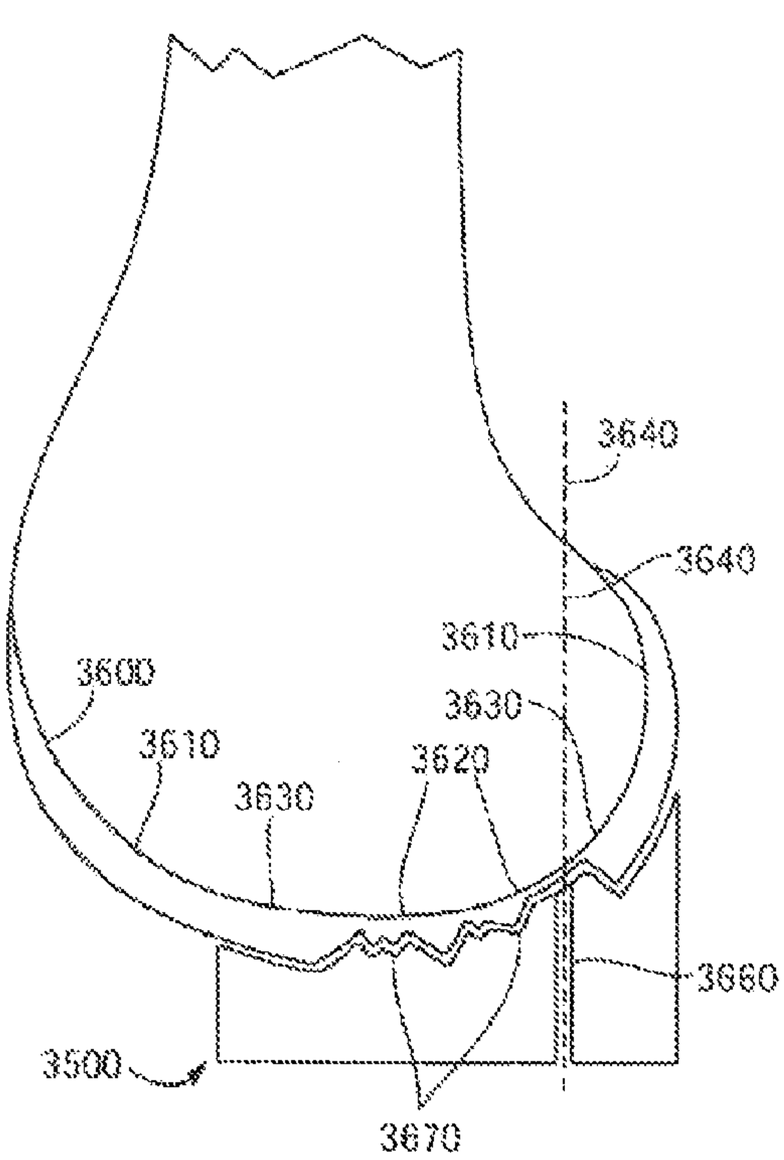

FIG. 26D

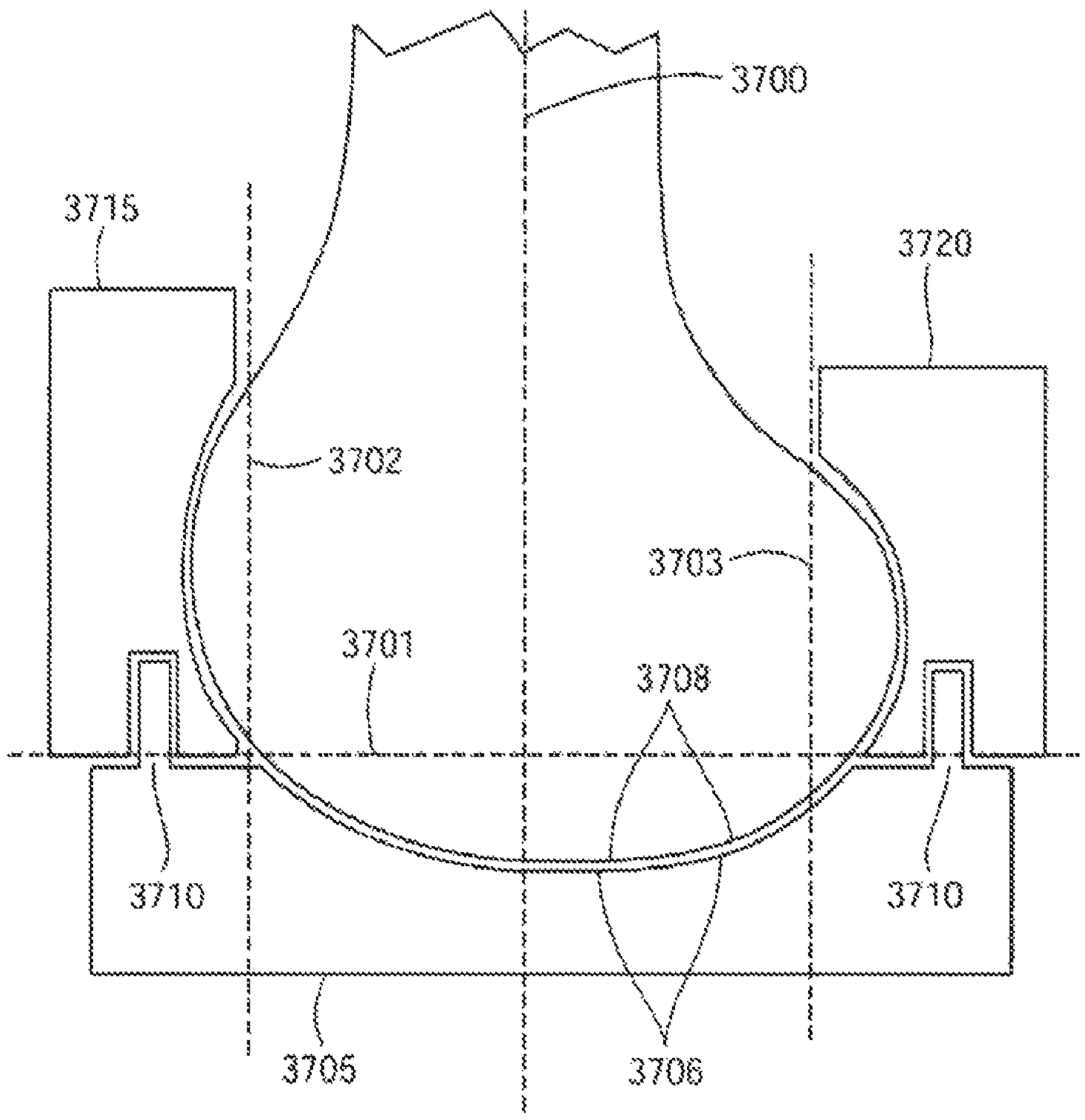

FIG. 27A

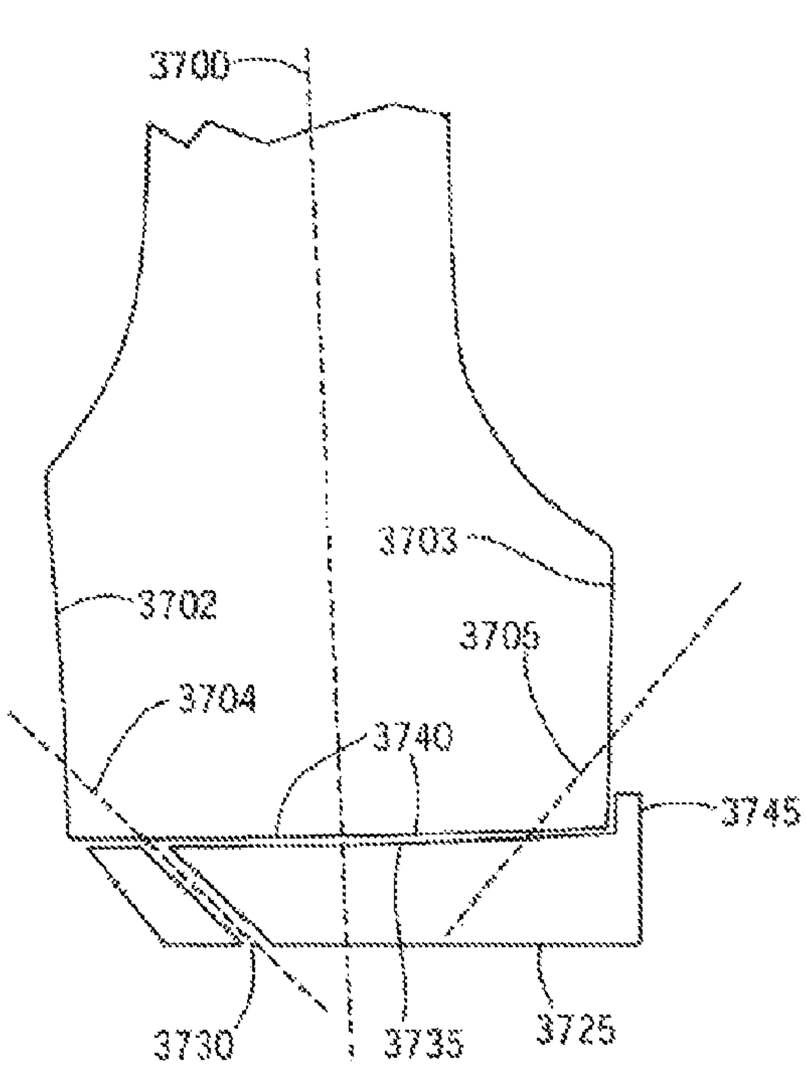

FIG. 27B

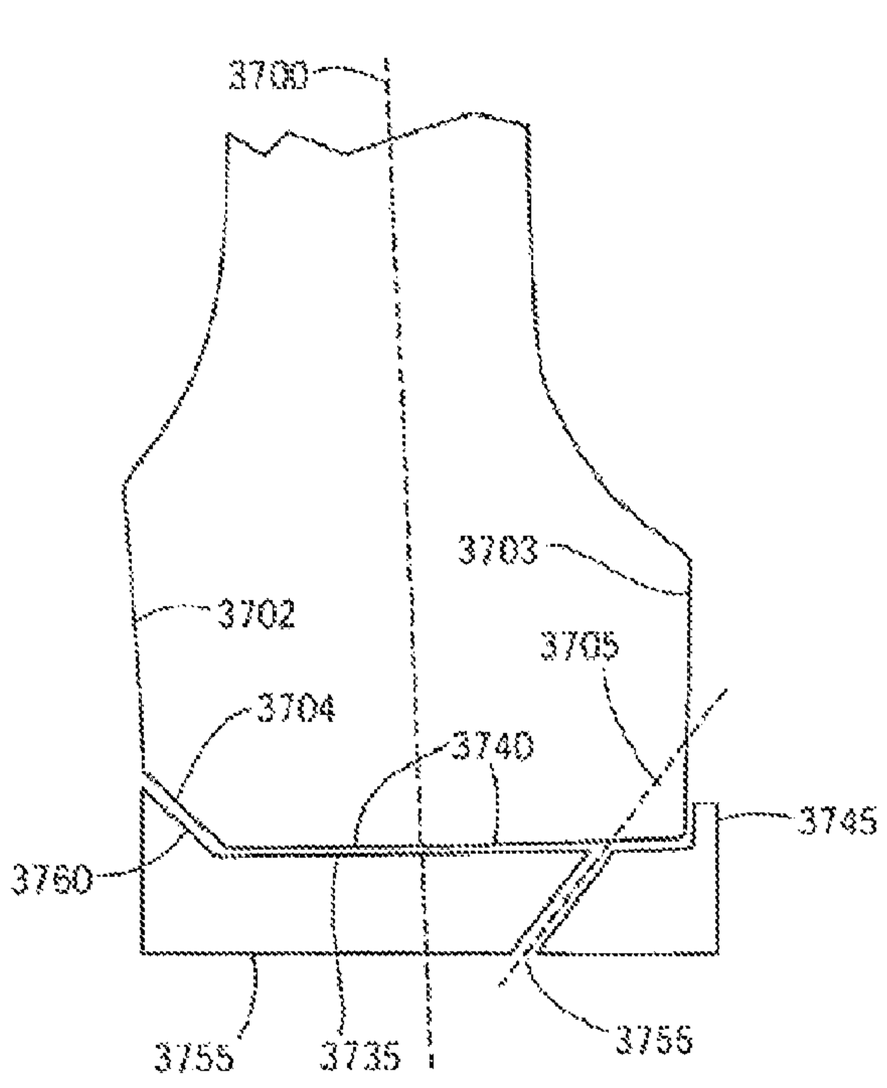

FIG. 27C

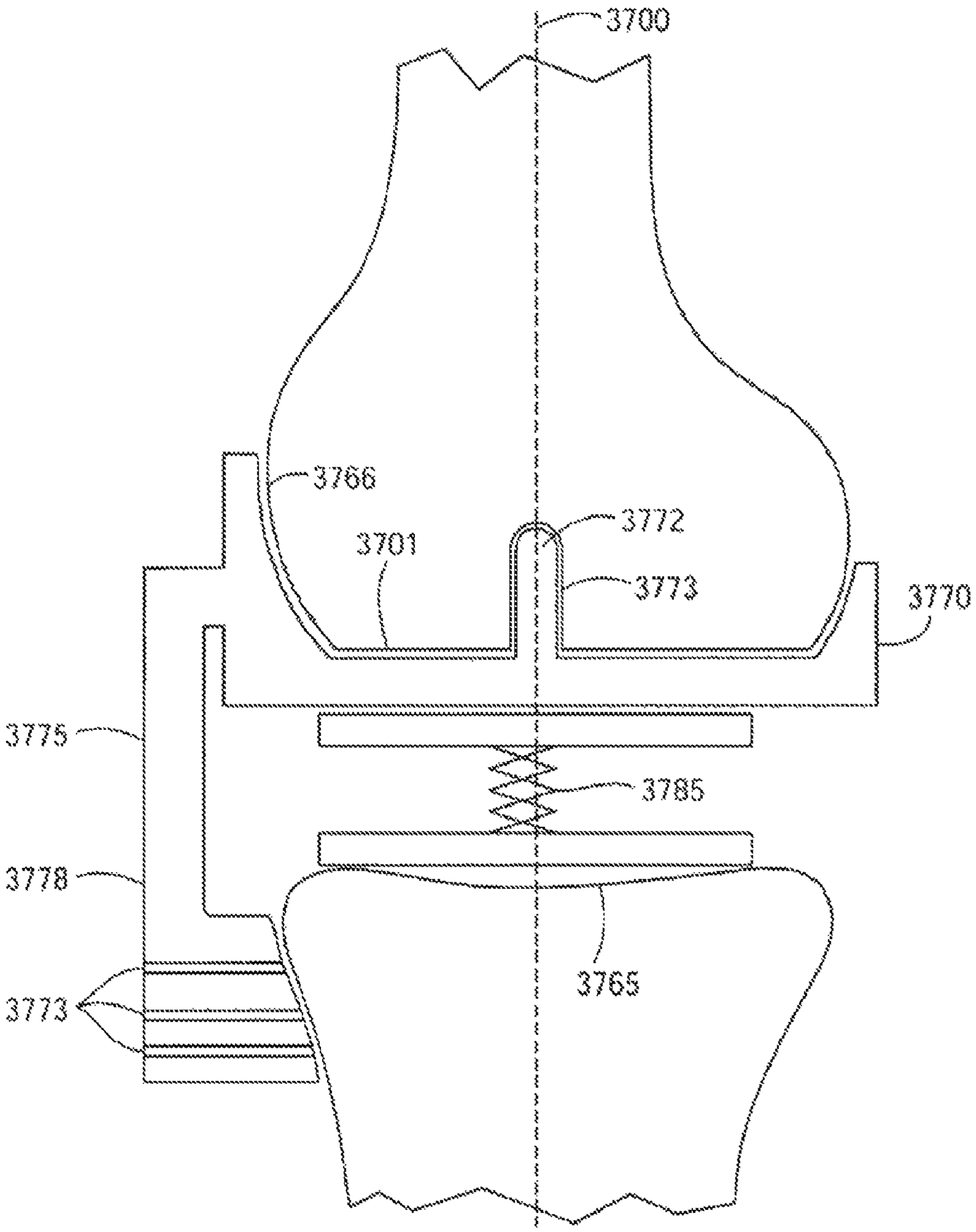

FIG. 27D

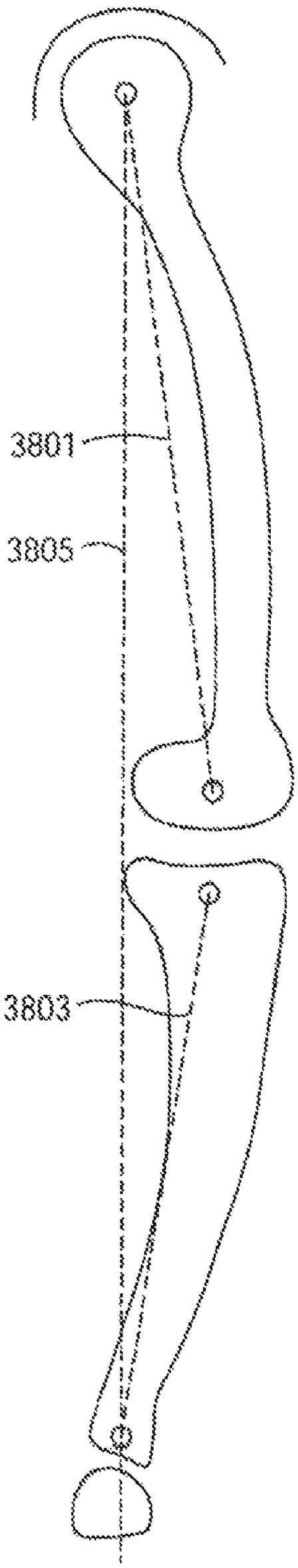
3801
3805
3803

FIG. 28

Perform Imaging Test, e.g. CT, MRI, Through Hip, Knee, Ankle Joint
Determine Leg Length Discrepancy
Determine Preferred Implant Size
Optional
Determine Preferred General Neck Cut Postion To Correct Leg Length Discrepancy For Optional General Component Placement

FIG. 29

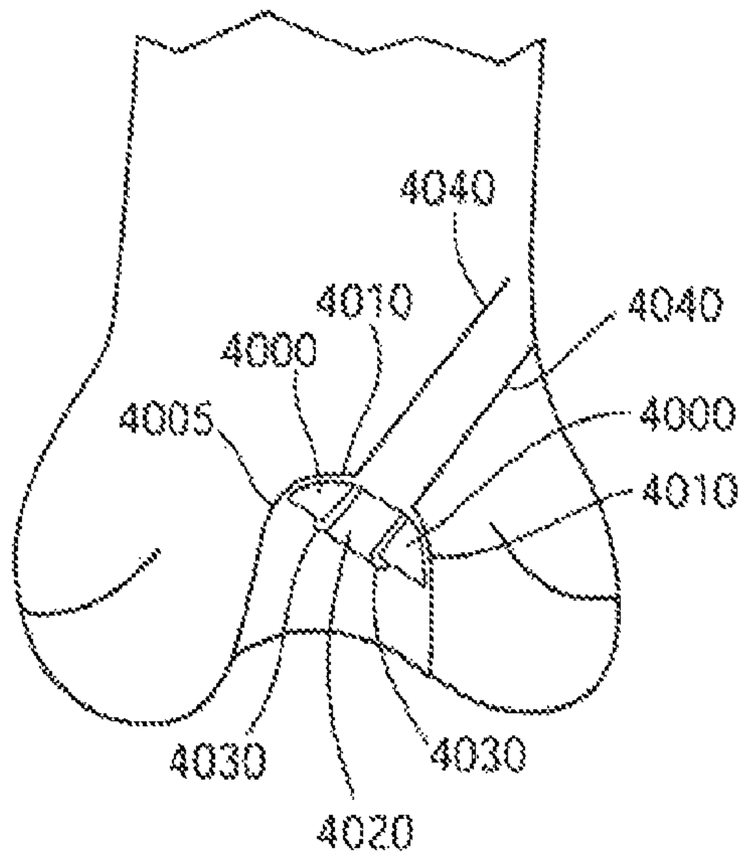

FIG. 30A

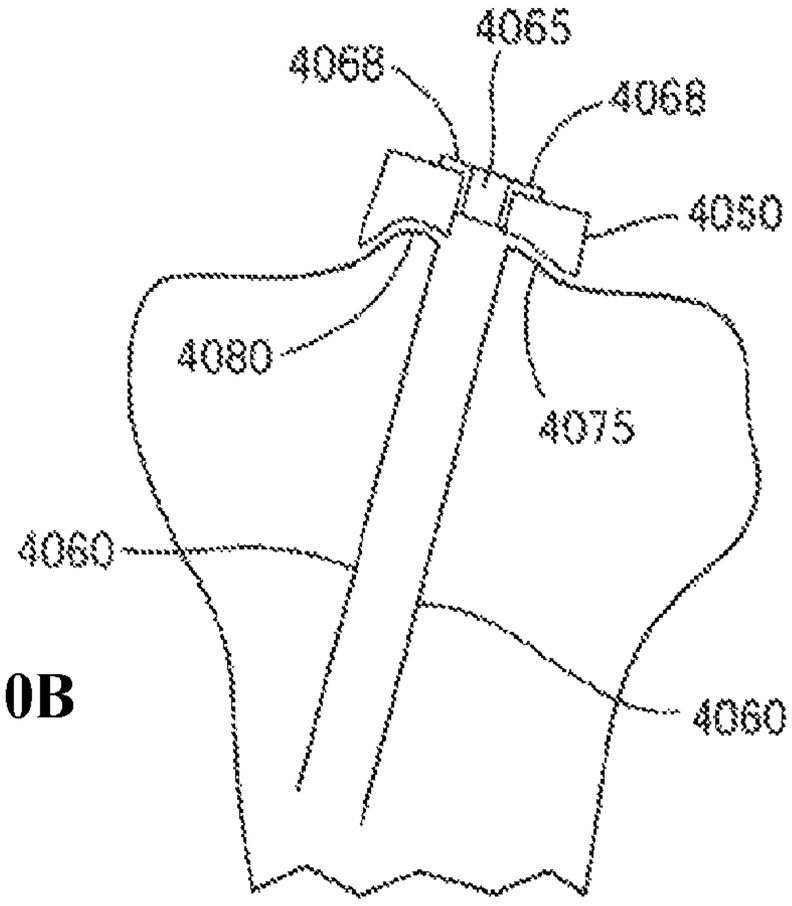

FIG. 30B

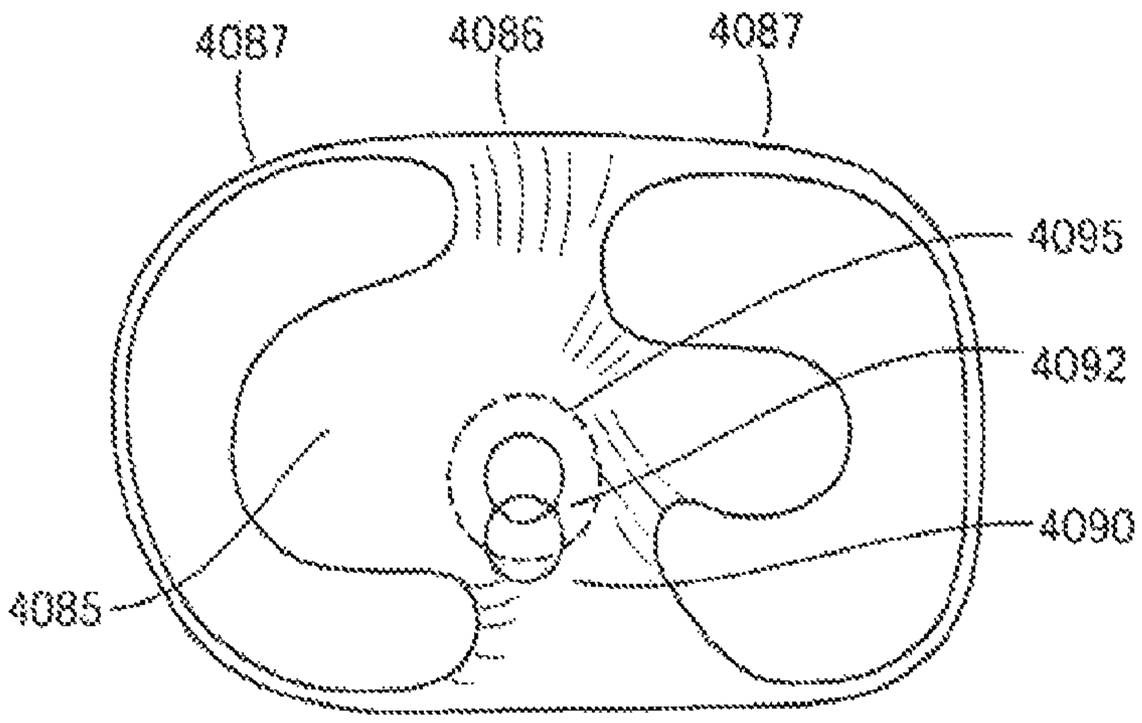

FIG. 30C

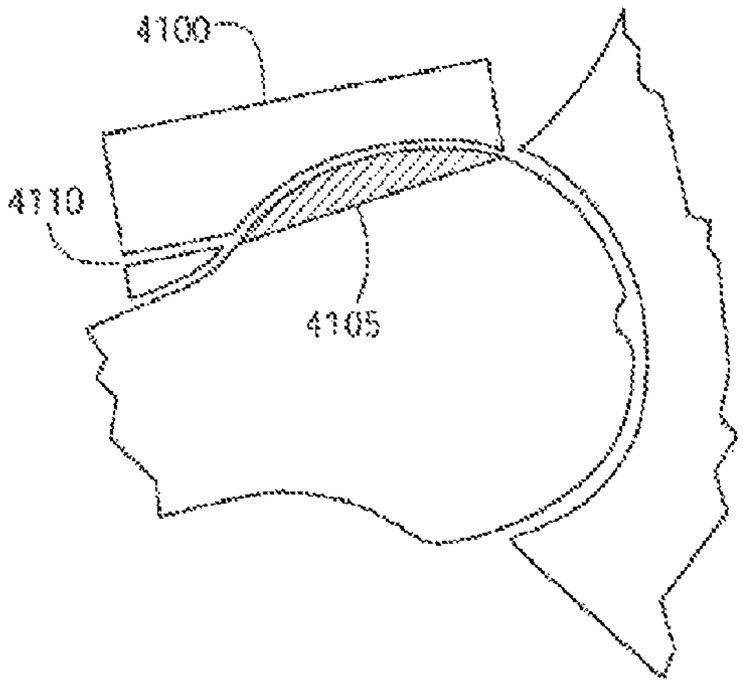

FIG. 31

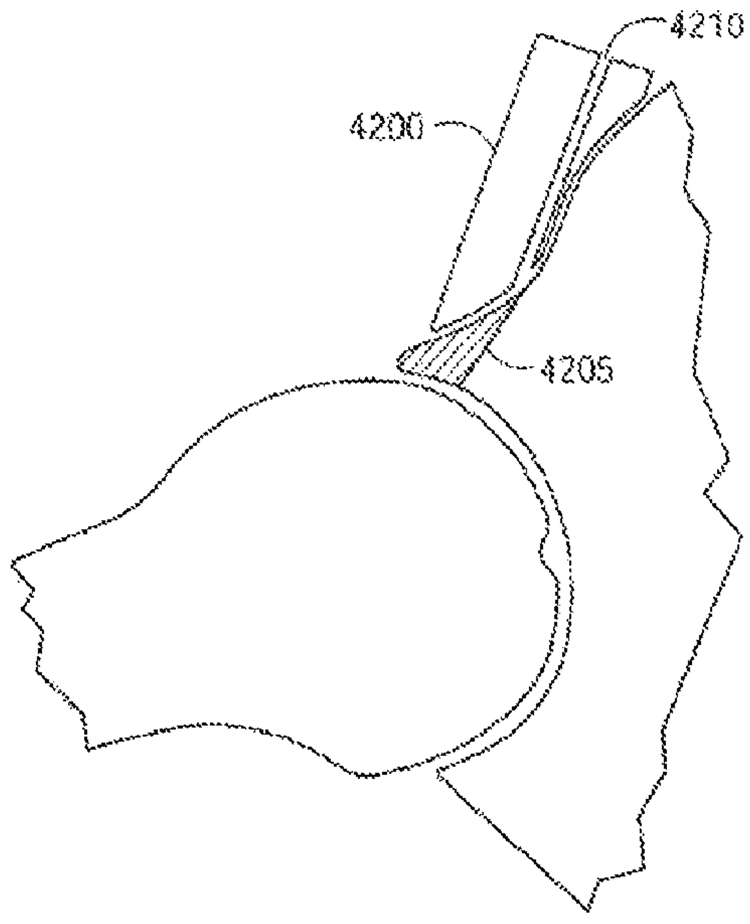

FIG. 32

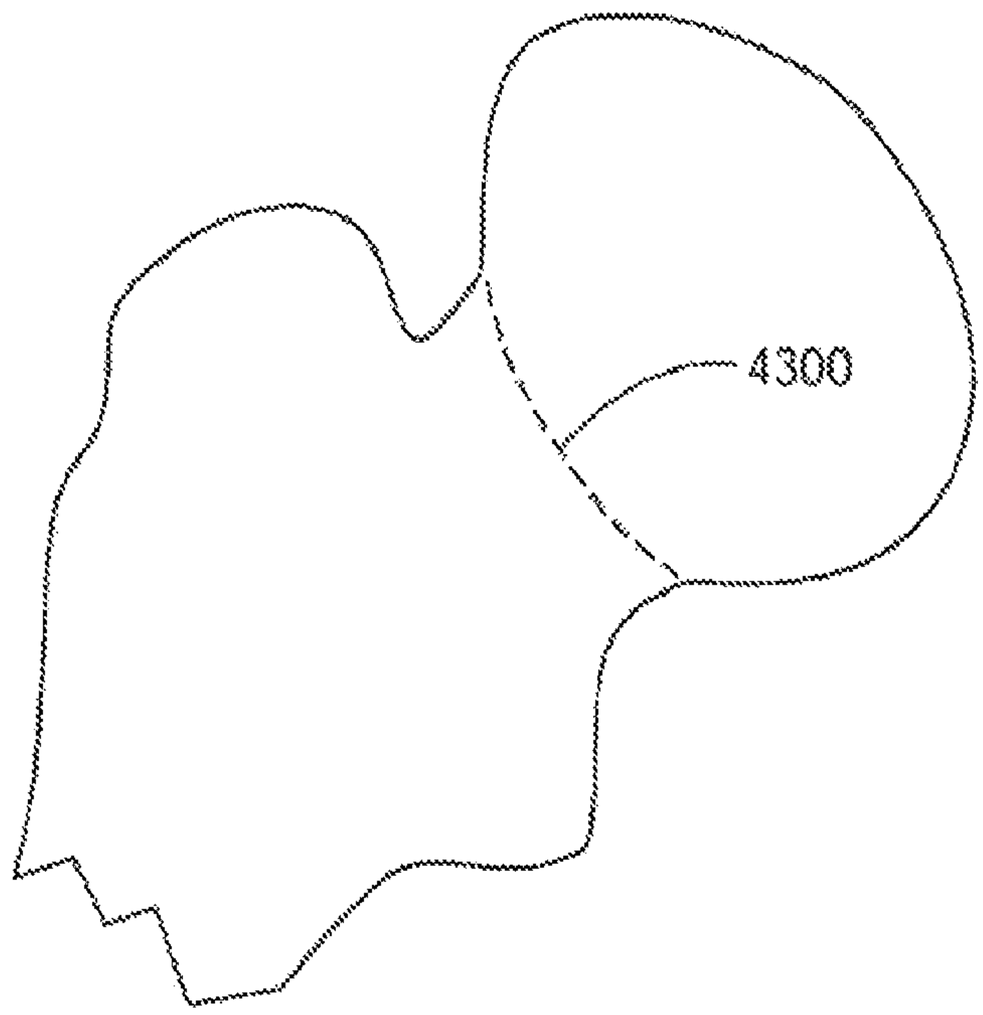

FIG. 33

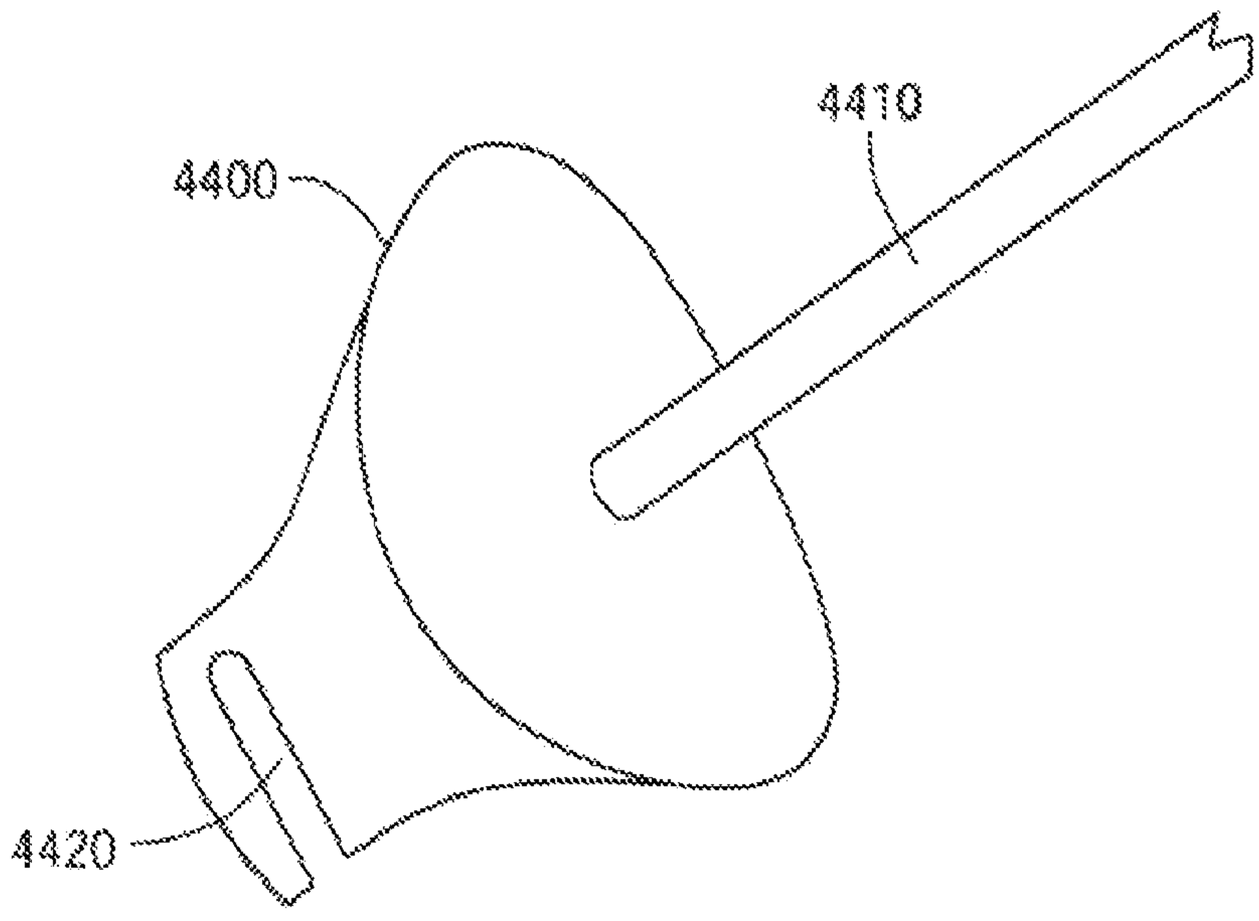

FIG. 34

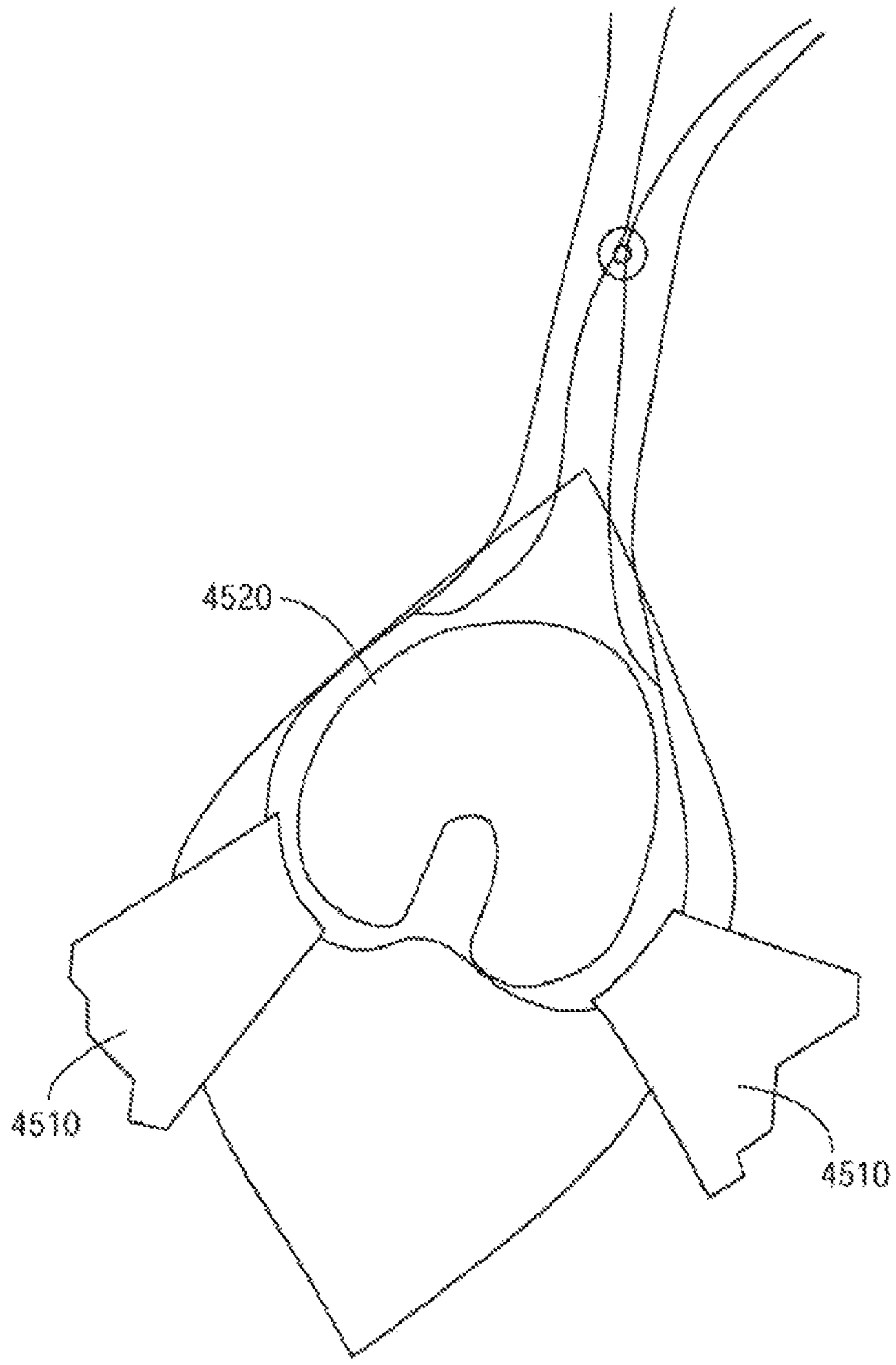

FIG. 35

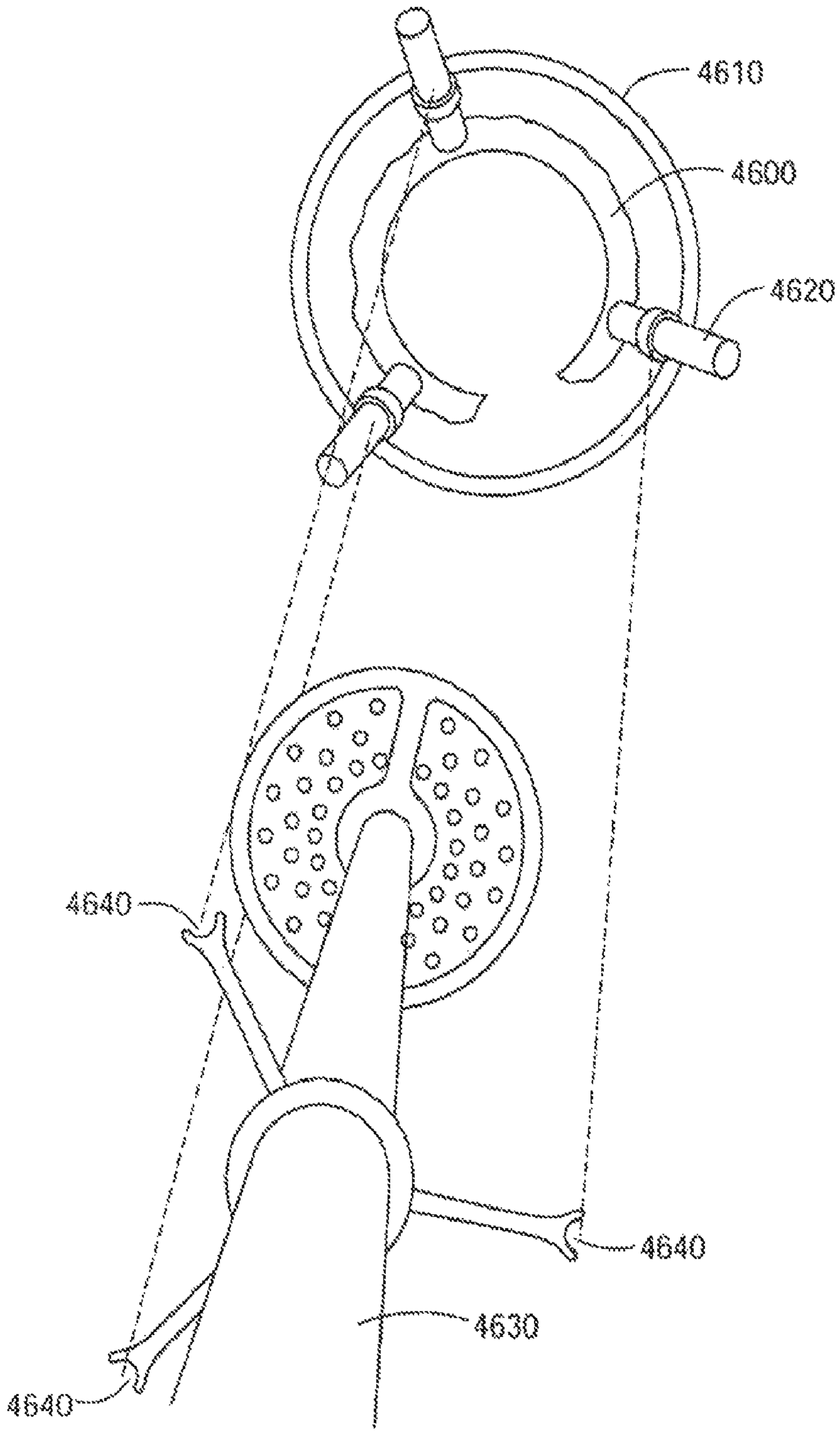

FIG. 36

REVISION SYSTEMS, TOOLS AND METHODS FOR REVISING JOINT ARTHROPLASTY IMPLANTS

RELATED APPLICATIONS

This application claims the benefit of: U.S. Ser. No. 61/523,756, entitled "Revision Systems, Tools and Methods for Revising Joint Arthroplasty Implants," filed Aug. 15, 2011, the disclosure of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

This disclosure relates to orthopedic methods, systems and prosthetic devices and more particularly relates to methods, systems and devices for articular resurfacing and for correcting failed surgical resurfacing and/or replacement implants. The disclosure also includes surgical tools, molds and/or jigs designed to achieve optimal cut planes in a joint in preparation for installation of a joint revision implant.

BACKGROUND OF THE INVENTION

Joint arthroplasties can be highly invasive and often require surgical resection of the entirety, or a majority of the, articular surface of one or more bones involved in the repair. In various procedures, the marrow space can be fairly extensively reamed in order to fit the stem of the prosthesis within the bone. Reaming results in a loss of the patient's bone stock and over time subsequent osteolysis will frequently lead to loosening of the prosthesis. Further, the area where the implant and the bone mate can degrade over time requiring the prosthesis to eventually be replaced. Since the patient's bone stock is limited, the number of possible replacement surgeries is also limited for joint arthroplasty. In short, over the course of 15 to 20 years, and in some cases even shorter time periods, the patient can run out of therapeutic options ultimately resulting in a painful, non-functional joint and/or requiring fusion or partial-fusion of the joint.

Current joint replacement and/or resurfacing implants, and the surgical corrections associated with implanting such devices, are generally accepted to be of finite duration. That is, assuming the patient's continued survival and/or continued use of the joint, every joint replacement and/or repair procedure will eventually require further surgery to repair and/or replace a failed or failing joint implant.

Failure of an implant and/or surgical correction can be a result of various causes. The implant may fracture, loosen or disassemble in some manner, or components may simply wear out and/or cease to properly function after prolonged use. Similarly, implant failure may be due to failure of the underlying support and/or anchoring structures, either due to continued progression of disease or pursuant to unexpected and/or excessive stresses. Moreover, an implant may fail where it has been malpositioned, or where it is experiencing unexpected/unacceptable loading for a variety of factors. Another contributing failure factor could be excessive pain generated and/or felt at the implant site. Other failure factors can include excessive debris generation, scar tissue intrusion into the joint space and/or unacceptable inflammation/swelling of the joint, uncontrollable infection at the implant site, and or development of necrosis, cysts, malignant neoplasm or other localized or systemic disease necessitating implant removal.

Regardless of the underlying cause, the removal of a failed implant generally necessitates a surgical intervention to remove or otherwise revise the original "failed" implant. Such a procedure also typically involves the placement of a subsequent or "revision" implant in the joint space, to correct the underlying joint function and/or otherwise address additional hard and soft tissue damage that may have occurred during the initial implant removal process and/or during subsequent preparation and placement of the revision implant. However, because a significant and potentially unknown amount of the original anatomical support structure is generally removed during the original implant surgery to place the original implant (now failed or failing), because additional native support structures may be removed with the failed implant, because the amount of further degradation of the anatomical support structure (post original surgery) is generally unknown or undetermined prior to removal of the failed implant during the revision surgery and because "artifacts" from the failed or failing implant often distort or otherwise mask anatomical or other features obtained using non-invasive imaging methods, there remains a significant need for improvements in the planning and execution of revision surgeries.

SUMMARY OF THE INVENTION

Current surgical revision procedures typically fail to utilize many sources of highly relevant patient and/or implant related information in planning and executing implant revision procedures. Moreover, the information available to a surgeon (and/or information that is presented to the surgeon) is generally not properly assessed for accuracy and/or cross-referenced/compared to other available relevant information to ensure accurate reflection of the condition of the patient's anatomy and/or the failed implant. The failure to assess multiple sources of information accurately, the failure to cross-reference and/or evaluate such information to create a more comprehensive picture of the failed implant and the patient's disease state, and the failure to provide a treating surgeon with an accurate pre-operative evaluation of the failed implant, the patient's anatomy, the disease state and/or the information regarding the potential surgical site significantly reduces the opportunity for a surgeon to correct the failed implant in a "least-invasive" and/or "most effective" manner. Moreover, the failure to have such information available during the planning and implant design phase may result in designing or choosing an incorrect/unsuitable implant and/or an implant that requires removal of healthy bone stock which could have been preserved for future use if the patient's anatomy were appropriately assessed.

In addition, this disclosure further includes the realization that one or more components of a failed or failing implant can often be utilized as one or more accurate reference points to facilitate the repair or replacement of a failed or failing partial or total joint replacement implant. In current revision surgery, a surgeon initially removes the failed implant components, and then prepares the anatomical support structure for the revision implant. Because much of the supporting anatomical structure may have been removed and/or modified (during the original surgery) to accommodate the original failed implant, and because addition anatomical degradation, anatomical structure removal and/or remodeling may have occurred prior to the revision surgery, a significant amount of time and effort, and a significant number of surgical tools, are utilized by the surgeon to locate desired anatomical alignment and/or positioning relative to any "virgin" anatomical reference points (i.e., intramedullary canal reference points, etc.). However, much of the additional alignment efforts can be readily reduced or obviated by the use of anatomical reference points

from the existing implant components, which can often be readily visualized via non-invasive imaging methods. When desired reference planes and/or reference positions can be identified and/or determined relative to such implant reference points (such as through an electronic evaluation system utilizing non-invasive imaging information), such reference points can be particularly useful as anatomical reference points for the planning and/or conduct of the surgery. Where surgical reference tools and/or jigs incorporate surfaces that match or otherwise substantially conform to some portion of the "failed implant," and are connected to or otherwise positioned relative to the "failed implant" prior to component removal (or other displacement of the component relative to the patient's joint), the failed implant can provide a highly accurate reference for subsequent surgical steps, including the placement of anatomical reference markers (i.e., alignment pins, etc.) or for aligning surgical cutting and or drilling/reaming tools for the creation of desired cutting planes/openings. Moreover, because implant "failure" can often be attributed to the failure of one component or portion of a component (i.e., a tibial stem will loosen while the femoral stem remains intact, or a condylar component will fracture with the remainder of the femoral component attached to the femur), the remaining component or component portions can often be utilized as a highly accurate reference position as well.

This disclosure describes systems, devices and methods for collecting and assessing multiple sources of patient, implant and potentially general population anatomical data, cross-referencing and evaluating the various data sources, and providing an evaluated output for a surgeon and/or implant designer/manufacturer to use in choosing, designing, manufacturing and implanting a replacement or "revision" implant in a selected patient or patients.

The various embodiments of systems, devices and methods discussed herein, including the various systems for collecting, assessing, utilizing and presenting multiple sources of patient and/or other surgical data, may be particularized or personalized for a selected "target audience," such as for a surgeon for planning and performing a surgical implant revision procedure, for an implant designer for designing a revision implant, or for a patient who wished to visualize and/or evaluate the outcome of a knee replacement procedure. Such output may comprise different data, different presentation methods, differing evaluations and/or analysis or various combinations particularized based upon an intended use for the information. In a similar manner, various embodiments may compare and evaluate prior scan image data relative to later scan data and create an output "map" or other presentation of the patient's anatomy, highlighting areas of bone growth or reduction, as well as changes in bone quality (i.e., increases/decreases in cancellous or cortical bone quality or quantity) as well as other tissue types (i.e., changes in articular cartilage and/or soft tissue quality and/or scarification). Such outputs could be extremely useful in diagnosing and/or treating underlying disease or other issues prior to, during or after implant or implant revision surgery.

In addition, this disclosure describes utilizing one or more portions of an existing "failed implant," either alone or in combination with other natural or artificial "anatomical features," as one or more anatomical reference points to assist in the planning, surgical preparation and/or alignment of surgical cutting instruments and/or to facilitate placement of a revision implant.

The current disclosure also contemplates the use of various pre-operative anatomical and "failed implant" data in the design and implantation of a desired revision implant. For example, where an implant has fractured or otherwise failed in some manner (such, for example, due to repetitive loading and wear over an extended period of time), the pre-operative data as well as other data may be utilized to determine the failure mode(s) of the implant, and an implant design approach can be tailored to desirably alleviate or account for such potential failure after implantation of the revision implant. Where such failure has been due to long term repetitive wear, the revision implant and associated surgical procedure could be chosen to "correct" of modify such loading in the joint, or the implant/procedure could be modified to increase the ability of the implant to withstand such loads and/or wear, such as by thickening the implant dimensions and/or utilizing harder or more durable materials. Similar design changes could be utilized where patient implants have failed due to excessive stress, such as where the patient participates in particular high-impact sports or the like. Such "improved implants" might require additional or differing anatomical support (i.e., a larger joint space to accommodate a thicker implant, potentially requiring some additional bone resection in various regions), which could alter the anticipated surgical procedure, but potentially result in an implant having a significantly better long-term outcome than one not tailored to accommodate specific loading conditions and/or real-world performance. Various embodiments contemplate the use of such additional modeling data in implant design, as well as design of surgical tools and jigs to facilitate the implantation of such implant.

The various embodiments of systems, devices and methods discussed herein can also desirably utilize pre-operative data to assess and potentially accommodate unusual and/or unexpected anatomical situations, such as ideal alignment with the articular surfaces and the resultant joint congruity. Poor alignment and poor joint congruity can, for example, lead to instability of the joint. In the knee joint, instability typically manifests as a lateral instability of the joint. Lateral instability may manifest itself in various ways, including pain, loosening of the implant and/or excessive wear and/or implant failure.

There is also a need for tools that increase the accuracy of positioning of a revision implant as well as increasing the accuracy of cuts made to the bone in a joint in preparation for surgical implantation of, for example, a revision system for replacing a failed artificial joint implant. This disclosure provides novel devices and methods for replacing a portion (e.g., diseased area and/or area slightly larger than the diseased area) of a patient's joint (e.g., cartilage and/or bone) with a non-pliable, non-liquid (e.g., hard) implant material, where the implant achieves a near anatomic fit with the surrounding structures and tissues of the patient's joint. In cases where the devices and/or methods include an element associated with the underlying articular bone, this disclosure also provides that the bone-associated element achieves a near anatomic alignment with the subchondral bone. This disclosure also provides for the preparation of an implantation site with one or more bone cuts/resections, e.g., a single cut, a few relatively small cuts, one or more chamfer cuts. This disclosure also provides for the preparation of an implantation site with other modifications, such as burring or reaming of the articular surface or underlying bone.

In various aspects, this disclosure includes a method for providing joint or articular replacement material, the method comprising the step of producing articular replacement material of selected dimensions (e.g., size, thickness and/or curvature).

In another aspect, this disclosure includes a method of making joint replacement implants, the method comprising the steps of (a) measuring the dimensions (e.g., thickness,

curvature and/or size) of the intended implantation site or the dimensions of the area surrounding the intended implantation site; and (b) providing replacement material that conforms to the measurements obtained in step (a). In certain aspects, step (a) comprises measuring the thickness of the cartilage surrounding the intended implantation site and measuring the curvature of the cartilage surrounding the intended implantation site. In other embodiments, step (a) comprises measuring the size of the intended implantation site and measuring the curvature of the cartilage surrounding the intended implantation site. In other embodiments, step (a) comprises measuring the thickness of the cartilage surrounding the intended implantation site, measuring the size of the intended implantation site, and measuring the curvature of the cartilage surrounding the intended implantation site. In other embodiments, step (a) comprises reconstructing the shape of healthy cartilage surface at the intended implantation site. Various embodiment include similar measurements and modeling of "failed implant" components and surrounding anatomical structures in planning and designing of revision implants and other replacement materials.

In any of the methods described herein, one or more components of the articular replacement material (e.g., the implant) can be non-pliable, non-liquid, solid or hard. The dimensions of the replacement material can be selected following intraoperative measurements. Measurements can also be made using imaging techniques such as ultrasound, MRI, CT scan, x-ray imaging obtained with x-ray dye and fluoroscopic imaging. A mechanical probe (with or without imaging capabilities) can also be used to select dimensions, for example an ultrasound probe, a laser, an optical probe and a deformable material or device.

In any of the methods described herein, the revision implant can be designed and made for an individual patient, or selected (for example, from a pre-existing library of repair systems), grown from cells and/or hardened from various materials. Furthermore, in any of the methods described herein the implant, e.g., a pre-made or pre-existing implant selected for a patient, can also be shaped (e.g., manually, automatically or by machine), for example using mechanical abrasion, laser ablation, radiofrequency ablation, cryoablation and/or enzymatic digestion, as well as material additive technologies including laser sintering, welding, adhering, etc. In any of the methods described herein, the various materials can comprise synthetic materials (e.g., metals, liquid metals, polymers, alloys or combinations thereof) or biological materials such as stem cells, fetal cells or chondrocyte cells.

In yet another aspect, this disclosure provides a method of determining the curvature of an articular surface, the method comprising the step of intraoperatively measuring the curvature of the articular surface using a mechanical probe. The articular surface can comprise cartilage and/or subchondral bone. In a still further aspect, this disclosure provides a method of producing an articular replacement material comprising the step of providing an articular replacement material that conforms to the measurements obtained by any of the methods of described herein.

In yet another aspect, an articular repair system comprising (a) cartilage replacement material, wherein said cartilage replacement material has a curvature similar to surrounding, adjacent, underlying or opposing cartilage; and (b) at least one non-biologic material, wherein said articular surface repair system comprises a portion of the articular surface equal to, smaller than, or greater than, the weight-bearing surface that is provided. In certain embodiments, the cartilage replacement material is non-pliable (e.g., hard hydroxyapatite, etc.). In certain embodiments, the system exhibits biomechanical (e.g., elasticity, resistance to axial loading or shear forces) and/or biochemical properties similar to articular cartilage. The first and/or second component can be bioresorbable and, in addition, the first or second components can be adapted to receive injections.

Any of the repair systems or prostheses described herein (e.g., the external surface) can comprise a polymeric material, for example attached to said metal or metal alloy. Any of the repair systems can be entirely composed of polymer. Further, any of the systems or prostheses described herein can be adapted to receive injections, for example, through an opening in the external surface of said cartilage replacement material (e.g., an opening in the external surface terminates in a plurality of openings on the bone surface). Bone cement, polymers, Liquid Metal, therapeutics, and/or other bioactive substances can be injected through the opening(s). In certain embodiments, bone cement is injected under pressure in order to achieve permeation of portions of the marrow space with bone cement, such as through, for example, a fenestrated stem or cannulated screw. In addition, any of the repair systems or prostheses described herein can be anchored in bone marrow or in the subchondral bone itself. One or more anchoring extensions (e.g., pegs, pins, etc.) can extend through the bone and/or bone marrow. Any anchoring extensions, e.g., pegs or pins, can be porous or porous coated, e.g., to facilitate bone in-growth.

In another aspect, a method of designing an articular implant comprising the steps of obtaining multiple images of a joint, of an associated implant and/or combinations thereof. In various embodiments the images can be from multiple angles and/or at different times during the patient's treatment history. The images can be cross-referenced and evaluated against each other as well as against non-patient database information (such as, for example, a database of normalized individuals from a general or specific population group), and a resulting output of the patient's anatomical features and/or estimated anatomical features can be provided. The output may then be used to design appropriate surgical tools, jig and implants for use in surgical repair of the failed implant. The images can include, for example, an intraoperative image including a surface detection method using any techniques known in the art, e.g., mechanical, optical, ultrasound, and known devices such as MRI, CT, ultrasound, digital tomosynthesis and/or optical coherence tomography images.

In yet another aspect, described herein are systems for evaluating the fit of an articular repair system into a joint, the systems comprising one or more computing means capable of superimposing a three-dimensional (e.g., three-dimensional representations of at least one articular structure and of the articular repair system) or a two-dimensional cross-sectional image (e.g., cross-sectional images reconstructed in multiple planes) of a joint and an image of an articular repair system to determine the fit of the articular repair system (including revision systems). The computing means can be: capable of merging the images of the joint and the articular repair system into a common coordinate system; capable of selecting or designing an articular repair system having the best fit; capable of rotating or moving the images with respect to each other; and/or capable of highlighting areas of poor alignment between the articular repair system and the surrounding articular surfaces. The three-dimensional representations can be generated using a parametric surface representation. The system may perform multiple steps automatically, in response to user intervention, or any combination thereof.

In yet another aspect, surgical tools for preparing a joint to receive an implant are described, for example a tool compris-

ing one or more surfaces or members that conform at least partially to the shape of the articular surfaces of the joint (e.g., a femoral condyle and/or tibial plateau of a knee joint), of non-joint anatomy (e.g., femoral neck features), of opposing joint surfaces and/or of relevant articular or non-articular surfaces of the "failed implant" or implant component. For example, a surface or at least a portion of a surface of a surgical tool as described herein has a shape that is substantially a negative of a portion of a surface of the joint, which can be a portion of an articular surface, a portion of non-articular or non-joint surface, etc.

In certain embodiments, the tool comprises Lucite silastic and/or other polymers or suitable materials. The tool can be re-useable or single-use. The tool may be made from one or more biodegradable materials such that, for example, a single-use tool can be readily disposed of without any significant, additional medical waste. The tool can be comprised of a single component or multiple components. In certain embodiments, the tool comprises an array of adjustable, closely spaced pins. In any embodiments described herein, the surgical tool can be designed to further comprise an aperture or guide therein, for example one or more apertures or guides having dimensions (e.g., diameter, depth, etc.) smaller or equal to one or more dimensions of the implant and/or one or more apertures or guides. Such apertures or guides can direct and/or control movement of one or more surgical instruments, e.g., a surgical saw, drill, reamer or broach. Such apertures or guides can be adapted to receive one or more injectables. Any of the tools described herein can further include one or more curable (hardening) materials or compositions, for example that are injected through one or more apertures in the tool and which solidify to form an impression of the articular surface.

In still another aspect, a method of evaluating the fit of an articular or joint repair system into a joint is described herein, the method comprising obtaining one or more three-dimensional images (e.g., three-dimensional representations of at least one articular structure and of the articular repair system) or two-dimensional cross-sectional images (e.g., cross-sectional images reconstructed in multiple planes) of a joint, wherein the joint includes at least one defect or diseased area and optionally a failed or failing implant or component(s) thereof; obtaining one or more images of one or more articular repair systems designed to repair the defect or diseased area; and evaluating the images to determine the articular repair system that best fits the defect (e.g., by superimposing the images to determine the fit of the articular repair system into the joint). In certain embodiments, the images of the joint and the articular repair system are merged into a common coordinate system. The three-dimensional representations can be generated using a parametric surface representation. In any of these methods, the evaluation can be performed by manual visual inspection and/or by computer (e.g., automated). The images can be obtained, for example, using a C-arm system and/or radiographic contrast.

In accordance with another embodiment, a surgical tool includes a template. The template has at least one contact surface for engaging a surface associated with a joint and/or surface of a "failed implant" or component(s) thereof. The at least one contact surface substantially conforms with the underlying surface(s). For example, at least a portion of the at least one contact surface includes a shape that is substantially a negative of at least a portion of the underlying surface(s). The at least one contact surface is optionally substantially transparent or semi-transparent. The template further includes at least one guide aperture for directing movement of a surgical instrument, e.g., a saw, drill, reamer or broach.

In accordance with related embodiments, the surface may be an articular surface, a non-articular surface, a cartilage surface, a weight bearing surface, a non-weight surface, a bone surface and/or a surface of an existing implant, implant component and/or "failed implant." The joint has a joint space, with the surface either within the joint space or external to the joint space. The template may include a mold. The template may include at least two pieces, the at least two pieces including a first piece that includes one or more of the at least one contact surfaces, the second piece including one or more of the at least one guide apertures or guide surfaces. The at least one contact surface may include a plurality of discrete contact surfaces.

In still further embodiments, the template may include a reference element, such as a pin or aiming device, for establishing a reference plane relative to at least one of a mechanical axis and an anatomical axis of a limb. In other embodiments, the reference element may be used for establishing an axis to assist in correcting an axis deformity.

In accordance with another embodiment, a method of joint arthroplasty is provided. The method includes obtaining images of a joint and/or joint implant, wherein the image(s) includes surfaces associated with the joint and/or joint implant. A template is created having at least one contact surface that conforms with the surface(s). The template includes at least one guide aperture or guide surface or element for directing movement of a surgical instrument. The template is positioned such that the contact surface abuts the surface(s) in a predefined orientation.

In related embodiments of the invention, the joint surface is at least one of an articular surface, a non-articular surface, a cartilage surface, a weight bearing surface, a non-weight bearing surface, a bone surface and/or a surface of an existing implant, implant component and/or "failed implant." The joint has a joint space, wherein the surface may be within the joint space or external to the joint space. The at least one contact surface may include a plurality of discrete contact surfaces. Creating the template may include rapid prototyping, milling and/or creating a mold, the template furthermore may be sterilizable and/or biocompatible. The rapid prototyping may include laying down successive layers of plastic. The template may be a multi-piece template. The multi-piece template may include a first piece that includes one or more of the at least one contact surfaces, and a second piece that includes one or more of the at least one guide apertures or guide surface or element. Obtaining the image may include determining dimensions of bone underlying the cartilage, and adding a predefined thickness to the bone dimensions, the predefined thickness representing the cartilage thickness. Adding the predefined thickness may be a function of at least one of an anatomic reference database, an age, a gender, and race matching. Obtaining the imaging may include performing an optical imaging technique, an ultrasound, a CT, a spiral CT, and/or an MRI.

In further related embodiments, the method may further include anchoring the contact surface to the cartilage. The anchoring may include using at least one of k-wire and adhesive. The anchoring may include drilling a bit through the cartilage, and leaving the bit in place. The anchoring may include forming the template to normal joint surface, arthritic joint surface or the interface between normal and arthritic joint surface or combinations thereof.

In still further related embodiments, the template may include a reference element. The method may include establishing, via the reference element, a reference plane relative to at least one of a mechanical axis and an anatomical axis of a limb. The mechanical axis may extend from a center of a hip

to a center of an ankle. Alternatively, an axis may be established via the reference element that is used to align surgical tools in correcting an axis deformity.

In further related embodiments, the method further includes performing at least one of a muscle sparing technique and a bone sparing technique. An incision for inserting the template may be equal to or less than one of 15 cm, 13 cm, 10 cm, 8 cm, and 6 cm. At least a portion of the template may be sterilized. Sterilizing may include heat sterilization and/or sterilization using gas. The sterilized portion may include a mold.

In accordance with another embodiment, a method of joint arthroplasty is presented. The method includes obtaining image(s) associated with a joint. A template is created having at least one contact surface that conforms with a surface associated with the joint or "failed implant" and/or component(s) thereof, the template including a reference element and at least one guide aperture or guide surface or element for directing movement of a surgical instrument. The template is aligned in an orientation on the joint such that the reference element establishes a reference plane relative to a mechanical axis of a limb. The template is anchored to the joint/implant such that the contact surface abuts the joint in said orientation. The mechanical axis may extend, for example, from a center of a hip to a center of an ankle. A surgical tool may be aligned using the reference element to correct an axis deformity.

In accordance with still another embodiment, a surgical tool includes a template. The template includes a mold having at least one contact surface for engaging a joint and/or "failed implant" surface. The at least one contact surface substantially conforms with the underlying surface(s). The mold is made of a biocompatible material. Furthermore, the mold is capable of heat sterilization without deforming. The template includes at least one guide aperture or guide surface or guide element for directing movement of a surgical instrument and/or reference marker (i.e., alignment pin, etc). In accordance with related embodiments, the mold may be capable of heat sterilization without deformation. The contact surface may be made of polyphenylsulfone.

In accordance with related embodiments, the method may further include using the second template to direct a surgical cut on the tibia. Anchoring the second template may occur subsequent or prior to anchoring the first template. At least one of the first and second templates may include a mold. The first contact surface may substantially conform with the femoral joint surface. The second contact surface may substantially conform with the tibial joint surface.

In accordance with another embodiment, a method of performing joint arthroplasty includes obtaining a first image associated with a first joint, obtaining a second image of a second joint, and optionally obtaining a third image of a third joint. A mechanical axis associated with the first joint and the second joint and optionally the third joint is determined. A template is provided for enabling surgery to correct an anatomic abnormality associated with at least one of the first, second and/or third joint.

In another embodiment, gait, loading and other physical activities as well as static positions of a joint may be simulated using a computer workstation. The template and the resultant surgical procedures, e.g. cuts, drilling, rasping, can be optimized using this information to achieve an optimal functional result. For example, the template and the resultant implant position may be optimized for different degrees of flexion and extension, internal or external rotation, abduction or adduction. Thus, the templates may be used to achieve motion that is optimized in one, two or more directions.

In accordance with related embodiments, the template may include at least one contact surface for engaging a surface associated with the first joint, the second joint and/or the third joint, the at least one contact surface substantially conforming with the surface. The template may include at least one guide aperture or guide surface or guide element for directing movement of a surgical instrument.

In further related embodiments, obtaining the first image may include imaging one of at least 5 cm, at least 10 cm, at least 15 cm, at least 20 cm, at least 25 cm, at least 30 cm, and at least 35 cm beyond the first joint. Obtaining the first image/and or second image and/or the third image may include performing a CT or an MRI. Performing the MRI may include obtaining a plurality of MRI scans. Optionally, two or more imaging modalities can be used and information obtained from the imaging modalities can be combined.

In accordance with another embodiment, a method of performing joint arthroplasty includes obtaining and/or deriving (using various methods described herein) a computer image of a surface associated with a first joint. At least one deformity seen in the computer image is removed pertaining to the surface, so as to form an improved anatomic or functional result. The at least one deformity is removed from the surface to create a modified surface. A template is provided based, at least in part, on the removal of the deformity. The template includes at least one contact surface for engaging the modified surface, the at least one contact surface substantially conforming with the modified surface.

In accordance with another embodiment, a method of performing joint arthroplasty includes obtaining a computer image of a surface associated with a first joint. At least one deformity seen in the computer image is removed and/or evaluated such as a biomechanical or anatomical axis deformity, so as to form an improved anatomic or functional result. The at least one deformity is removed in the surgical planning by modifying the shape or position of a template including the shape and/or position of guide apertures, guide surface or guide elements. A template is provided based, at least in part, on the removal of the deformity. The template includes at least one contact surface for engaging the joint surface. The shape and/or position of guide apertures, guide surface or guide elements is selected or designed to achieve a correction of the deformity.

In accordance with related embodiments, the template may be used in a surgical procedure. The template may include at least one guide aperture, guide surface or guide elements, the method further including using the at least one guide aperture, guide surface or guide elements to direct movement of a surgical instrument. The at least one deformity may include a osteophyte, a subchondral cyst, and/or an arthritic deformation.

In accordance with another embodiment, a method of performing joint arthroplasty includes obtaining an image of a surface associated with a first joint, the image including at least one deformity. A template is provided, based at least in part on the image, the template having at least one contact surface for engaging portions of the surface free of the deformity. The at least one contact surface substantially conforms with the portions of the surface. The template is used in a surgical procedure.

In accordance with related embodiments, the template may include at least one guide aperture, guide surface or guide elements, the method further including using the at least one guide aperture, guide surface or guide elements to direct movement of a surgical instrument. The at least one deformity may include a osteophyte, a subchondral cyst, and/or an arthritic deformation.

In accordance with another embodiment, a method of performing joint arthroplasty includes obtaining an image of a surface associated with a joint and/or "failed implant," the image including at least subchondral bone. A template is provided, based at least in part on the image. The template includes at least one contact surface substantially conforming with the subchondral bone and/or a surface of the "failed implant." Residual cartilage is removed from the bone surface in areas where the at least one contact surface is to contact the subchondral bone. The template is positioned such that the at least one contact surface abuts the subchondral bone and/or "failed implant" surface in a predefined orientation.

In accordance with another embodiment, a method of performing joint arthroplasty includes providing a template. The template is fixated to bone and/or "failed implant" surface(s) associated with a joint without performing any cuts to the joint. The template may be used in a surgical procedure.

In accordance with related embodiments, fixating may include drilling into the bone and leaving a drill bit in the bone. An image of a surface associated with a joint may be obtained, the template having at least one contact surface that conforms with the surface.

A method of placing an implant into a joint is also provided. The method comprises the steps of imaging the joint using a C-arm system, obtaining a cross-sectional image with the C-arm system, and utilizing the image for placing the implant into a joint.

In accordance with another embodiment, a system for joint arthroplasty includes a first template. The first template includes at least one surface for engaging a first surface of a joint, the surface including a portion that substantially conforms to, matches or has a shape that is substantially a negative of one or more portions or all of the first surface. The first template further includes at least one guide for directing movement of a surgical instrument. A linkage cross-references at least one surgical tool relative to said guide and relative to one of an anatomical and a mechanical axis.

In accordance with related embodiments, the surgical tool may be a second template, the second template including at least one guide for directing movement of a surgical instrument. The second template may include a surface that includes a portion that substantially conforms to at least a portion of a second joint surface. The second joint surface may oppose the first joint surface. At least one guide of the second template may direct the surgical instrument in at least one of a cut, a milling, and a drilling oriented in a predefined location relative to said first template and adapted in shape, size or orientation to an implant shape. The shape and/or position of the at least one guide of the first template may be based, at least in part, on one or more axis related to said joint. The linkage may be an attachment mechanism, which may cause the first template to directly contact the at least one surgical tool, or alternatively, attaches the first template and the at least one surgical tool such that the first template and the at least one surgical tool do not directly contact each other. The linkage may allow for rotation relative to one of an anatomical and a mechanical axis. The first template may include a removably attached block, the block including the at least one guide of the first template.

In accordance with another embodiment, a system for joint arthroplasty is presented that includes a first template. The first template includes at least one surface for engaging a first surface of a joint, the surface including a portion that substantially conforms to one or more portions or all of the first surface. The first template further includes at least one guide for directing movement of a surgical instrument. A linkage cross-references at least one surgical tool on a second surface of the joint opposing the first surface.

In accordance with another embodiment, a system for joint arthroplasty is presented that includes a first template. The first template includes at least one first template surface for engaging a first surface of a joint and/or "failed implant," the first template surface substantially conforming to, matching, or having a shape that is substantially a negative of one or more portions or all of the first surface. The first template further includes at least one guide for directing movement of a surgical instrument. A second template includes at least one second template surface for engaging a second surface of a joint. In certain embodiments, the second template includes at least a surface portion that substantially conforms to, matches, or has a shape that is substantially a negative of one or more portions or all of the second anatomical surface or "failed implant" surface. In certain embodiments, the second template includes at least a surface portion that engages at least a portion of the first template through an attachment or engagement mechanism, e.g., a snap fit or telescopic engagement. The second template further includes at least one guide for directing movement of a surgical instrument. In certain embodiments, a linkage cross-references the first template and the second template.

In accordance with another embodiment, a system for joint arthroplasty includes a first template. The first template includes at least one surface for engaging a first surface of a joint and/or "failed implant," the surface substantially conforming to, matching, or having a shape that is substantially a negative of one or more portions or all of the first surface. The first template further includes at least one guide for directing movement of a surgical instrument. A linkage cross-references at least one surgical tool, wherein the linkage allows for rotation and/or other movement relative to one of an anatomical and a mechanical axis associated with the joint.

In accordance with another embodiment, a method of joint arthroplasty includes positioning at least one contact surface of a first template onto a first surface of a joint or failed implant. A second template is cross-referenced to the first template to align position of the second template on a second surface of the joint, the second template including at least one guide. Movement of the surgical instrument is directed using the at least one guide of the second template relative to said guide and relative to one of an anatomical and a mechanical axis.

In accordance with related embodiments, the at least one contact surface of the first template substantially conforms to, matches, or has a shape that is substantially a negative of at least a portion of the first surface and/or failed implant surface. The method may further include obtaining electronic image data of the joint, and determining a shape of the at least one contact surface of the first template based, at least in part, on electronic image data.

In accordance with other related embodiments, the method may further include, prior to directing movement of the surgical instrument, positioning at least one contact surface of the second template to the second joint surface. The at least one contact surface of the second template may substantially conform to, match, or have a shape that is substantially a negative of one or more portions or all of the second surface. The method may further include obtaining electronic image data of the joint, and determining a shape of the at least one contact surface of the second template based, at least in part, on electronic image data.

In accordance with yet further related embodiments, cross-referencing the second template to the first template may includes attaching the second template to the first template.

Attaching the second template to the first template may include performing intraoperative adjustments. The second template is attached to the first template via a pin, and wherein performing intraoperative adjustments include rotating the second template around the pin. The method may further include performing an intraoperative adjustment on the position of the second template on the second surface of the joint, wherein performing the intraoperative adjustment includes using one of spacers, ratchets, and telescoping devices. The method may further include performing an intraoperative adjustment on the position of the second template on the second surface of the joint, wherein performing the intraoperative adjustment includes adjusting for at least one of joint flexion, joint extension, joint abduction, and joint rotation. Directing movement of the surgical instrument using the at least one guide of the second template may include making one or more cuts or drill holes, the method further comprising implanting a joint prosthesis as a function of the one or more cuts or drill holes. The first template may include at least one guide, the method further comprising directing movement of a surgical instrument using the at least one guide of the first template. Directing movement of the surgical instrument using the at least one guide of the first template may include making one or more cuts or drill holes, the method further comprising implanting a joint prosthesis as a function of the one or more cuts or drill holes. Directing movement of the surgical instrument using the at least one guide of the second template may include making at least one of a cut, a drill hole, and a reaming, the method further comprising implanting a joint prosthesis.

In still further related embodiments, the first surface of the joint may be a femoral surface, and the second surface of the joint may be a tibial surface (or surfaces of implant components attached thereto). The method may further include obtaining electronic image data of a joint, determining the at least one of a mechanical axis and an anatomical axis of the joint based, at least in part, on the electronic image data, wherein the shape and/or position of the guide of the second template is based, at least in part, on the at least one of the mechanical axis and the anatomical axis. The electronic image data may be obtained pre-operatively, intraoperatively, optically, an MRI, a CT, and/or a spiral CT. The first template may include a thickness based, at least in part, on at least one of a thickness of an implant to be attached to the first surface of the joint or implant and a desired space between two opposing surfaces of the joint.

In accordance with another embodiment, a method of joint arthroplasty includes positioning at least one contact surface of a first template onto a first surface of a joint and/or implant. A second template is cross-referenced to the first template to align position of the second template on a second surface of the joint, the second surface opposing the first surface. The second template includes at least one guide. Movement of the surgical instrument is directed using the at least one guide of the second template.

In accordance with another embodiment, a method of joint arthroplasty includes positioning at least one contact surface of a first template onto a first surface of a joint, wherein the at least one contact surface of the first template includes a portion that substantially conforms to at least a portion of the first surface of the joint. A second template is cross-referenced to the first template to align position of the second template onto a second surface of the joint, the at least one contact surface of the second template includes a portion that substantially conforms to at least a portion of the second surface of the joint. The second template includes at least one guide. Movement of the surgical instrument is directed using the at least one guide of the second template.

In accordance with another embodiment, a method of joint arthroplasty includes positioning at least one contact surface of a first template onto a first surface of a joint. A second template is cross-referenced to the first template to align position of the second template on a second surface of the joint, the second template including at least one guide. Cross-referencing allows rotation of the second template relative to one of a biomechanical and an anatomical axis. Movement of the surgical instrument is directed using the at least one guide of the second template.

In accordance with another embodiment, a method of joint arthroplasty includes obtaining electronic image data of a joint, and determining width space of the joint based, at least in part, on the electronic image data. A template is provided that includes at least one guide for directing movement of a surgical instrument, wherein at least one of the shape and position of the guide is based, at least in part, on the width space of the joint.

In accordance with related embodiment, the template may include at least one surface for engaging a surface of a joint, the at least one surface of the template substantially matches, conforms to, or has a shape that is substantially a negative of at least a portion or all of the surface of the joint. Obtaining electronic image data may include at least one of a CT scan, MRI scan, optical scan, and a ultrasound imaging. Obtaining electronic image data may include obtaining image data of a medial space, a lateral space, anterior space, and/or posterior space of the joint. At least two of the lateral space, anterior space, and posterior space of the joint may be compared. Obtaining image data may be performed in two dimensions or three dimensions, and may include assessment, evaluation, cross-referencing and correction of data from multiple image sources and/or from images of the joint and/or implant from different periods of time or at different times in the patient's treatment regime. Determining width of the joint may include measuring the distance from the subchondral bone plate of one articular surface to the subchondral bone plate of the opposing articular surface. Alternatively, determining width of the joint may include measuring the distance from the subchondral bone plate of one articular surface to the subchondral bone plate of the opposing articular surface. Obtaining the image data of the joint may be performed in at least one of joint flexion, joint extension, and joint rotation. At least one of the shape and position of the guide may be further based, at least in part, on the anatomical or mechanical axis alignment of the joint.

In accordance with another embodiment, a method of joint arthroplasty includes obtaining electronic image data of a joint, and determining cartilage loss associated with the joint based, at least in part, on the electronic image data. A template may be provided that includes at least one guide for directing movement of a surgical instrument so as to correct an axis alignment of the joint, wherein at least one of the shape and position of the guide is based, at least in part, on the cartilage loss. In a similar manner, another method of joint arthroplasty includes obtaining electronic image data of a joint and/or "failed implant," and determining changes in cartilage and/or underlying bone support of the anatomical support structure prior to planning and/or performing a "revision" implantation procedure based, at least in part, on the electronic image data.

In accordance with related embodiments, the method may further include measuring at least one axis associated with the joint. Measuring may include a standing x-ray, a weight bearing x-ray, a CT scout scan, a MRI localizer scan, a CT scan,

and/or a MRI scan. Obtaining image data may include a spiral CT, spiral CT arthography, MRI, optical imaging, optical coherence tomography, and/or ultrasound. The template may include at least one contact surface for engaging a surface of the joint and/or "failed implant," at least a portion of the contact surface substantially conforms to or matches one or more portions or all of the joint/implant surface.

In accordance with another embodiment, a method for joint arthroplasty includes obtaining electronic image data of a joint, and determining a plurality of measurements based, at least in part, on the image data. The measurements may be selected from at least one of an axis associated with the joint and a plane associated with the joint. A template is provided that includes at least one guide for directing movement of a surgical instrument, wherein at least one of the shape and position of the guide is based, at least in part, on the plurality of measurements.

In accordance with related embodiments, obtaining image data of the joint may include an x-ray, a standing x-ray, a CT scan, an MRI scan, CT scout scans, and/or MRI localizer scans. The plurality of measurements may include a plurality of axis, a plurality of planes, or a combination of an axis and a plane. The template may include at least one contact surface for engaging a surface of a joint, the at least one contact surface substantially conforms to, matches or has a shape that is substantially a negative of one or more portions or all of the joint surface.

In accordance with another embodiment, a surgical tool includes a template having a surface for engaging a joint or implant surface, and the template surface substantially conforms to, matches or has a shape that is substantially a negative of one or more portions or all of the joint or implant surface. The template further includes two or more guides for directing movement of a surgical instrument, wherein the shape and/or position of at least one of the guides is based, at least in part, on at least one axis related to said joint.

In accordance with related embodiments, the template further includes a block removably attached to the surface(s), the block including the two or more guides. The two or more guides may include at least one guide for a cut, a milling, and a drilling. A second surgical tool may be attached to the template, the second tool including at least one guide aperture for guiding a surgical instrument. At least one guide of the second surgical tool may guide a surgical instrument to make cuts that are parallel, non-parallel, perpendicular, or non-perpendicular to cuts guided by the first template.

In accordance with another embodiment, a method of joint arthroplasty includes performing an extended scan of a joint to obtain electronic image data that includes the joint and at least 15 cm or greater beyond the joint. At least one of an anatomical and a mechanical axis associated with the joint is determined based, at least in part, on the electronic image data. A template is provided that includes at least one guide for directing movement of a surgical instrument, wherein at least one of the shape and position of the guide is based, at least in part, on the at least one of the anatomical and the mechanical axis.

In accordance with related embodiments, the joint may be a knee joint, and performing the extended scan of a joint to obtain electronic image data includes obtaining electronic image data at least 15 cm, 20 cm, or 25 cm beyond the tibiofemoral joint space.

In accordance with another embodiment, a method of joint arthroplasty includes performing an imaging scan acquisition that obtains electronic image data through more than one joint. At least one of an anatomical axis and a mechanical axis associated with the joint is determined based, at least in part, on the electronic image data. A template is provided that includes at least one guide for directing movement of a surgical instrument, wherein at least one of the shape and position of the guide is based, at least in part, on the at least one of the anatomical and the mechanical axis.

In accordance with related embodiments, performing the imaging acquisition includes performing a CT, MRI, an X-ray, and/or a two-plane x-ray, wherein the CT and the MRI includes a slice, spiral, and/or volume acquisition. The guide may direct the movement of a surgical instrument to correct a varus deformity and/or a valgus deformity.

In accordance with another embodiment, a method of joint arthroplasty includes obtaining a first image of a joint in a first plane, wherein the first image generates a first image volume. A second image of a joint in a second plane is obtained, wherein the second image generates a second image data volume. The first and second image data volumes is combined to form a resultant image data volume, wherein the resultant image data volume is substantially isotropic. A template is provided based on the resultant image data volume, the template including at least one surface for engaging a first surface of a joint or implant, at least a portion of the surface substantially conforming to or matches (or having a shape that is substantially a negative of) one or more portions or all of the first joint or implant surface. The template further includes at least one guide for directing movement of a surgical instrument.

In accordance with related embodiments, obtaining the first image and the second image may includes a spiral CT, volumetric CT, and/or an MRI scan.

In accordance with another embodiment, a method for joint arthroplasty includes performing a first cut on a joint to create a first cut joint surface. Performing the first cut includes positioning at least one contact surface of a first template onto a first surface of a joint and/or "failed implant" or component thereof, the at least one contact surface having a shape that is substantially a negative of the first surface of the joint and/or "failed implant" or component thereof. The first template includes a guide for directing movement of a surgical instrument to perform the first cut. The first cut is cross-referenced to perform a second cut associated with an opposing surface of the joint.

In accordance with related embodiments, cross-referencing the first cut to make the second cut may include attaching a second template to the first template so as to assist positioning at least one contact surface of the second template onto a second surface of the joint. The second template includes a guide for directing movement of a surgical instrument to perform the second cut. The second template may include at least one contact surface portion that substantially conforms to, matches or has a shape that is substantially a negative of at least a portion of the second surface of the joint or a surface of an implant. Cross-referencing the first cut to make the second cut may include positioning at least one contact surface of a third template onto at least a portion of the first cut surface, and attaching a second template to the third template so as to position at least one contact surface of the second template onto a second surface of the joint. The at least one contact surface portion of the third template may substantially conform to, match or have a shape that is substantially a negative of the first cut surface. The first cut may be a horizontal femoral cut, with the second cut being a vertical femoral cut. The first cut may be femoral cut with the second cut being a tibial cut. The first cut may be a femoral cut, and the second cut is a patellar cut. The first cut may be an acetabular reaming and the second cut is a femoral cut.

In accordance with another embodiment, a method for joint arthroplasty includes positioning at least one contact surface of a template onto a surface of a joint or implant, the at least one contact surface substantially conforming to, matching or having a shape that is substantially a negative of at least a portion of the surface of the joint or implant. The template includes a guide for directing movement of a surgical instrument. The first template is stabilized onto the first surface.

In accordance with related embodiments, the method may further include obtaining electronic image data of the joint, and determining a shape of the at least one contact surface of the first template based, at least in part, on electronic image data. Stabilizing may include using k-wires, a screw, an anchor, and/or a drill bit left in place on the joint. Stabilizing may include positioning the contact surface on at least one or more concavities and convexities on the joint or implant. Stabilizing may include positioning the contact surface on at least one concavity and at least convexity on the joint or implant. Stabilizing may include positioning the contact surface, at least partially, on an arthritic portion of the joint and/or "failed implant" or component thereof. Stabilizing may include positioning the contact surface, at least partially, on an interface between a normal and an arthritic portion of the joint or implant. Stabilizing may include positioning the contact surface, at least partially, on one or more surfaces of the "failed implant." Stabilizing may include positioning the contact surface, at least partially, against an anatomic feature. The anatomic feature may be a trochlea, an intercondylar notch, a medial condyle and a lateral condyle, a medial trochlea and a lateral trochlea, a medial tibial plateau and a lateral tibial plateau, a fovea capities, an acetabular fossa, a tri-radiate cartilage, an acetabular wall, or an acetabular rim. Positioning the contact surface on the surface of the joint may include positioning the contact surface on, at least partially, a normal portion of the joint. Determining the position of the guide on the template may be based, at least in part, on ligament balancing and/or to optimize at least one of flexion and extension gap. The method may further include adjusting the position of the guide relative to the joint intraoperatively, using for example, a spacer, a ratchet device, and a pin that allows rotation.

In accordance with another embodiment, a method for joint arthroplasty includes positioning at least one contact surface of a template onto a surface of a patient's joint, such that the contact surface, at least partially or a portion thereof, substantially conforms to and rests on an interface between an arthritic and a normal portion of the patient's joint surface. The template includes a guide for directing movement of a surgical instrument. A surgical intervention is made on the joint with the surgical instrument based, at least in part, on the guide.

In accordance with another embodiment, a template includes at least one contact surface for positioning onto a surface of a joint, the contact surface at least partially or a portion thereof having a shape that is substantially a negative of (or substantially conforms to or matches) an interface between an arthritic and a normal portion of the joint surface. A guide directs movement of a surgical instrument.

In accordance with another embodiment, a method for joint arthroplasty includes positioning at least one contact surface of a template onto a surface of a joint, such that the contact surface, at least partially, rests on, and is substantially a negative of (or substantially conforms to or matches) of, an arthritic portion of the joint surface. The template includes a guide for directing movement of a surgical instrument. A surgical intervention is made on the joint with the surgical instrument based, at least in part, on the guide.

In accordance with another embodiment, a template includes at least one contact surface for positioning onto a surface of a joint, the contact surface at least partially being substantially a negative of (or substantially conforms to or matches) of a normal portion of the joint surface. The template includes a guide for directing movement of a surgical instrument.

In accordance with another embodiment, a method for joint arthroplasty includes performing a phantom scan of one of a MRI and CT instrument. Using the one of the an MRI and CT instrument, a scan on a joint is performed. A shape of the at least one contact surface of the first template is determined, based, at least in part, on the phantom scan and the scan of the joint and/or implant, the at least one contact surface having at least a portion that substantially matches (or conforms to or has a shape that is substantially a negative of) at least a portion of the surface of the joint or implant. The template includes a guide for directing movement of a surgical instrument.

In accordance with related embodiments, the phantom scan may be performed prior to the scan of the joint, the method further comprising adjusting the one of the MRI and the CT instrument. The phantom scan may be performed after performing the scan of the joint, wherein the scan of the joint is optimized based on the phantom scan.

In accordance with another embodiment, a method for joint arthroplasty includes determining a desired femoral component rotation for one of a uni-compartmental or total knee replacement. A template is provided that includes at least one guide for directing movement of a surgical instrument, attached linkage, and/or tool. At least one of the shape and position of the guide is based, at least in part, on the desired femoral component rotation.

In accordance with related embodiments, determining the desired femoral component rotation may include measuring one or more anatomic axis and/or planes relevant to femoral component rotation. The one or more anatomic axis and/or planes may be a transepicondylar axis, the Whiteside line, and/or the posterior condylar axis. The guide may direct a femoral cut, the method further comprising rotating the template so that the femoral cut is parallel to a tibial cut with substantially equal tension medially and laterally applied from medial and lateral ligaments and soft tissue.

In accordance with another embodiment, a method for joint arthroplasty includes determining a desired tibial component rotation for one of a uni- or bi-compartmental or total knee replacement. A tibial template is provided that includes at least one guide for directing movement of a surgical instrument, attached linkage, and/or tool. At least one of the shape and position of the guide is based, at least in part, on the desired tibial component rotation.

In accordance with related embodiments, determining the desired tibial component rotation may include measuring one or more anatomic axis and/or planes relevant to tibial component rotation. The one or more anatomic axis and/or planes may be at an anteroposterior axis of the tibia, and/or the medial one-third of the tibial tuberosity. The guide may direct a femoral cut, the method further comprising rotating the template so that the femoral cut is parallel to a tibial cut with substantially equal tension medially and laterally applied from medial and lateral ligaments and soft tissue.

In accordance with another embodiment, a method of hip arthroplasty includes determining leg length discrepancy and obtaining electronic image data of the hip joint. A template is provided that includes at least one guide for directing movement of a surgical instrument, attached linkage, and/or tool. The template includes at least one contact surface that is substantially a negative of (or substantially conforms to or

matches) of at least a portion of the femoral neck or femoral joint implant component, wherein at least one of the shape and position of the template and/or guide is based, at least in part, on the electronic image data.

In accordance with related embodiments, determining leg length discrepancy may include a standing x-ray of the leg, a CT scout scan, a CT, and/or an MRI. The guide may assist a surgical instrument in cutting the femoral neck.

In accordance with another embodiment, a method for joint arthroplasty includes determining a desired femoral component rotation for a hip. A template is provided that includes at least one guide for directing movement of a surgical instrument, attached linkage, and/or tool. At least one of the shape and position of the guide is based, at least in part, on the desired femoral component rotation.

In accordance with another embodiment, a method for joint arthroplasty includes determining a desired acetabular component rotation for a hip. An acetabular template is provided that includes at least one guide for directing movement of a surgical instrument, attached linkage, and/or tool. At least one of the shape and position of the guide is based, at least in part, on the desired acetabular component rotation.

In accordance with another embodiment, a method for joint arthroplasty includes determining a desired humerus component rotation for a shoulder. A template is provided that includes at least one guide for directing movement of a surgical instrument, attached linkage, and/or a tool. At least one of the shape and position of the guide is based, at least in part, on the desired humerus component rotation.

In accordance with another embodiment, a method for joint arthroplasty includes providing a template that includes at least one surface for engaging a surface of a joint or implant based, at least in part, on substantially isotropic input data. The surface includes at least a portion that has a shape that is substantially a negative of one or more portions or all of the joint or implant surface. The template includes at least one guide for directing movement of a surgical instrument.

In related embodiments, said input data is acquired using fusion of image planes, or substantially isotropic MRI and spiral CT.

In any of the embodiments and aspects described herein, the joint can be, without limitation, a knee, shoulder, hip, vertebrae, elbow, ankle, foot, toe, hand, wrist or finger. Moreover, the various embodiments described herein can assist in the assessment, planning, evaluation and execution of repair and/or replacement procedures for virtually any implant, including failed or failing hip, shoulder, elbow, foot, toe, hand, wrist or finger, ankle or knee implants as well as spinal implants such as fusion devices, disc replacement devices (i.e., Charite or ProDisk) and/or pedicle screws.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing features of this disclosure will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

FIG. **1**A is a flowchart depicting various methods according to various embodiments of this disclosure.

FIG. **1**B is a flowchart depicting various alternative methods according to various embodiments of this disclosure.

FIGS. **2**A-H illustrate, in cross-section, various stages of knee resurfacing, in accordance with various embodiments of this disclosure. FIG. **2**A shows an example of normal thickness cartilage and a cartilage defect. FIG. **2**B shows an imaging technique or a mechanical, optical, laser or ultrasound device measuring the thickness and detecting a sudden change in thickness indicating the margins of a cartilage defect. FIG. **2**C shows a weight-bearing surface mapped onto the articular cartilage. FIG. **2**D shows an intended implantation site and cartilage defect. FIG. **2**E depicts placement of an exemplary single component articular surface repair system. FIG. **2**F shows an exemplary multi-component articular surface repair system. FIG. **2**G shows an exemplary single component articular surface repair system. FIG. **2**H shows an exemplary multi-component articular surface repair system.

FIGS. **3**A-E, illustrate, in cross-section, exemplary knee imaging and resurfacing, in accordance with various embodiments of the invention. FIG. **3**A shows a magnified view of an area of diseased cartilage. FIG. **3**B shows a measurement of cartilage thickness adjacent to the defect. FIG. **3**C depicts placement of a multi-component mini-prosthesis for articular resurfacing. FIG. **3**D is a schematic depicting placement of a single component mini-prosthesis utilizing stems or pegs. FIG. **3**E depicts placement of a single component mini-prosthesis utilizing stems and an opening for injection of bone cement.

FIGS. **4**A-C, illustrate, in cross-section, other exemplary knee resurfacing devices and methods, in accordance with various embodiments of the invention. FIG. **4**A depicts normal thickness cartilage in the anterior and central and posterior portion of a femoral condyle and a large area of diseased cartilage in the posterior portion of the femoral condyle. FIG. **4**B depicts placement of a single component articular surface repair system. FIG. **4**C depicts a multi-component articular surface repair system.

FIGS. **5**A-B show single and multiple component devices, in accordance with various embodiments of the invention. FIG. **5**A shows an exemplary single component articular surface repair system with varying curvature and radii. FIG. **5**B depicts a multi-component articular surface repair system with a second component that mirrors the shape of the subchondral bone and a first component closely matches the shape and curvature of the surrounding normal cartilage.

FIGS. **6**A-B show exemplary articular repair systems having an outer contour matching the surrounding normal cartilage, in accordance with various embodiments. The systems are implanted into the underlying bone using one or more pegs.

FIG. **7** shows a perspective view of an exemplary articular repair device including a flat surface to control depth and prevent toggle; an exterior surface having the contour of normal cartilage; flanges to prevent rotation and control toggle; a groove to facilitate tissue in-growth, in accordance with one embodiment.

FIGS. **8**A-D depict, in cross-section, another example of an implant with multiple anchoring pegs, in accordance with various embodiments. FIG. **8**B-D show various cross-sectional representations of the pegs: FIG. **8**B shows a peg having a groove; FIG. **8**C shows a peg with radially-extending arms that help anchor the device in the underlying bone; and FIG. **8**D shows a peg with multiple grooves or flanges.

FIG. **9**A-B depict an overhead view of an exemplary implant with multiple anchoring pegs and depict how the pegs are not necessarily linearly aligned along the longitudinal axis of the device, in accordance with various embodiments.

FIGS. **10**A-E depict an exemplary implant having radially extending arms, in accordance with various embodiments of the invention. FIGS. **10**B-E are overhead views of the implant showing that the shape of the peg need not be conical.

FIG. **11**A illustrates a femur, tibia and fibula along with the mechanical and anatomic axes. FIGS. **11**B-E illustrate the tibia with the anatomic and mechanical axis used to create a

cutting plane along with a cut femur and tibia. FIG. **11**F illustrates the proximal end of the femur including the head of the femur.

FIG. **12** shows an example of a surgical tool having one surface matching the geometry of an articular surface of the joint, in accordance with one embodiment. Also shown is an aperture in the tool capable of controlling drill depth and width of the hole and allowing implantation of an insertion of implant having a press-fit design.

FIG. **13** is a flow chart depicting various methods of this disclosure used to create a mold for preparing a patient's joint for arthroscopic surgery.

FIG. **14**A depicts, in cross-section, an example of a surgical tool containing an aperture through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone. Dotted lines represent where the cut corresponding to the aperture will be made in bone. FIG. **14**B depicts, in cross-section, an example of a surgical tool containing apertures through which a surgical drill or saw can fit and which guide the drill or saw to make cuts or holes in the bone. Dotted lines represent where the cuts corresponding to the apertures will be made in bone.

FIGS. **15**A-R illustrate tibial cutting blocks and molds used to create a surface perpendicular to the anatomic axis for receiving the tibial portion of a knee implant.

FIGS. **16**A-O illustrate femur cutting blocks and molds used to create a surface for receiving the femoral portion of a knee implant. FIG. **16**P illustrates an axis defined by the center of the tibial plateau and the center of the distal tibia. FIG. **16***q* shows an axis defining the center of the tibial plateau to the femoral head. FIG. **16**R and **16**S show isometric views of a femoral template and a tibial template, respectively. FIG. **16**T illustrates a femoral guide reference tool attached to the femoral template. FIG. **16**U illustrates a sample implant template positioned on the chondyle. FIG. **16**V is an isometric view of the interior surface of the sample implant template, in accordance with an embodiment. FIG. **16**W is an isometric view of the tibial template attached to the sample implant. FIG. **16**X shows a tibial template that may be used, after the tibial cut has been made, to further guide surgical tools. FIG. **16**Y shows a tibial implant and femoral implant inserted onto the tibia and femur, respectively, after the above-described cuts have been made.

FIG. **17**A-G illustrate patellar cutting blocks and molds used to prepare the patella for receiving a portion of a knee implant.

FIG. **18**A-H illustrate femoral head cutting blocks and molds used to create a surface for receiving the femoral portion of a knee implant.

FIG. **19**A-D illustrate acetabulum cutting blocks and molds used to create a surface for a hip implant.

FIG. **20** illustrates a 3D guidance template in a hip joint, wherein the surface of the template facing the joint includes a portion that substantially matches at least a portion of the joint that is not affected by the arthritic process.

FIG. **21** illustrates a 3D guidance template for an acetabulum, wherein the surface of the template facing the joint includes a portion that substantially matches at least a portion of the joint that is affected by the arthritic process.

FIG. **22** illustrates a 3D guidance template designed to guide a posterior cut using a posterior reference plane. The joint facing surface of the template has a shape, at least in part, that is substantially a negative of at least of portions of the joint that are not altered by the arthritic process.

FIG. **23** illustrates a 3D guidance template designed to guide an anterior cut using an anterior reference plane, in accordance with one embodiment. The joint facing surface of the template substantially matches or conforms to, at least in part, one or more portions of the joint that are altered by the arthritic process.

FIG. **24** illustrates a 3D guidance template for guiding a tibial cut (not shown), wherein the tibia includes an arthritic portion. The template is designed to avoid the arthritic process by spanning across a defect or cyst.

FIG. **25** illustrates a 3D guidance template for guiding a tibial cut. The interface between normal and arthritic tissue is included in the shape of the template.

FIG. **26**A illustrates a 3D guidance template wherein the surface of the template facing the joint substantially conforms to at least portions of the surface of a joint that is healthy or substantially unaffected by the arthritic process. FIG. **26**B illustrates the 3D guidance template wherein the surface of the template facing the joint substantially matches at least portions of the surface of the joint that is healthy or substantially unaffected by the arthritic process. The diseased area is covered by the template, but the mold is not substantially in contact with it. FIG. **26**C illustrates the 3D guidance template wherein the surface of the template facing the joint includes a portion having a shape that is substantially a negative of one or more portions of the surface of the joint that are arthritic. FIG. **26**D illustrates the 3D guidance template wherein the template closely mirrors the shape of the interface between substantially normal or near normal and diseased joint tissue.

FIGS. **27**A-D show multiple molds with linkages on the same articular surface (A-C) and to an opposing articular surface (D).

FIG. **28** illustrates a deviation in the AP plane of the femoral and tibial axes in a patient.

FIG. **29** is a flow diagram showing a method wherein measured leg length discrepancy is utilized to determine the optimal cut height of a femoral neck cut for total hip arthroplasty.

FIGS. **30**A-C illustrate the use of 3D guidance templates for performing ligament repair.

FIG. **31** shows an example of treatment of CAM impingement using a 3D guidance template.

FIG. **32** shows an example of treatment of Pincer impingement using a 3D guidance template.

FIG. **33** shows an example of an intended site for placement of a femoral neck mold for total hip arthroplasty.

FIG. **34** shows an example of a femoral neck mold with handle and slot.

FIG. **35** shows an example of a posterior acetabular approach for total hip replacement.

FIG. **36** shows an example of a guidance mold used for reaming the site for an acetabular cup.

DETAILED DESCRIPTION OF THE INVENTION

The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of this disclosure as defined by the appended claims. Thus, this disclosure is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. To the extent necessary to achieve a complete understanding of this disclosure disclosed, the specification and drawings of all issued patents, patent publications, and patent applications cited in this application are incorporated herein by reference.

3D guidance surgical tools, referred to herein as a 3D guidance surgical templates, that may be used for surgical assistance may include, without limitation, using templates, jigs and/or molds, including 3D guidance molds. It is to be understood that the terms "template," "jig," "mold," "3D guidance mold," and "3D guidance template," shall be used interchangeably within the detailed description and appended claims to describe the tool unless the context indicates otherwise.

3D guidance surgical tools that may be used may include guide apertures. It is to be understood that the term guide aperture shall be used interchangeably within the detailed description and appended claims to describe both guide surface and guide elements.

As will be appreciated by those of skill in the art, the practice of this disclosure employs, unless otherwise indicated, conventional methods of x-ray imaging and processing, x-ray tomosynthesis, ultrasound including A-scan, B-scan and C-scan, computed tomography (CT scan), magnetic resonance imaging (MRI), optical coherence tomography, single photon emission tomography (SPECT) and positron emission tomography (PET) within the skill of the art. Such techniques are explained fully in the literature and need not be described herein. See, e.g., X-Ray Structure Determination: A Practical Guide, 2nd Edition, editors Stout and Jensen, 1989, John Wiley & Sons, publisher; Body CT: A Practical Approach, editor Slone, 1999, McGraw-Hill publisher; X-ray Diagnosis: A Physician's Approach, editor Lam, 1998 Springer-Verlag, publisher; and Dental Radiology: Understanding the X-Ray Image, editor Laetitia Brocklebank 1997, Oxford University Press publisher. See also, The Essential Physics of Medical Imaging (2^{nd} Ed.), Jerrold T. Bushberg, et al.

This disclosure provides systems, methods and compositions for repairing joints, particularly for repairing and/or replacing implants and implant components previously implanted into a patient's joint, as well as repairing articular cartilage and for facilitating the integration of a wide variety of cartilage repair materials into a subject. Among other things, the techniques described herein allow for the customization of implants and surgical tools to suit a particular subject, for example in terms of size, thickness, shapes and/or curvatures. Desirably, such tools can utilize and existing "failed implant" information and/or surfaces as one or more anatomical reference points to assist in the preparation, positioning and/or placement of a replacement implant for repairing a patient's joint.

When the shape (e.g., size, thickness and/or curvature) of the articular cartilage surface is an exact or near anatomic fit with the non-damaged cartilage or with the subject's original cartilage, the success of repair is enhanced. The repair material can be shaped prior to implantation and such shaping can be based, for example, on electronic images that provide information regarding curvature or thickness of any "normal" cartilage surrounding the defect and/or on curvature of the bone underlying the defect. Thus, the current invention provides, among other things, for minimally invasive methods for partial joint replacement. The methods will require only minimal or, in some instances, no loss in bone stock. Additionally, unlike with current techniques, the methods described herein will help to restore the integrity of the articular surface by achieving an exact or near anatomic match between the implant and the surrounding or adjacent cartilage and/or subchondral bone. Moreover, if the "failed implant" only requires replacement of one or more individual failed components, the procedure may be less invasive than a complete joint removal and replacement, and could thus be accomplished in a less-invasive and/or minimally-invasive fashion, desirably with commensurately less recovery time.

The various embodiments described in the present disclosure also contemplate the use of existing "failed implant" components or portions thereof as anchoring mechanisms, attachment points, anatomical reference structures and/or as components of the "revision implant" ultimately used in repairing the patient's joint. In some instances, components of the "failed implant" may be useful for a myriad of reasons, including if the "failed" implant component is well-fixed to the patient's anatomy and failure of the original "failed" implant was due to other implant components. In a similar manner, certain components of a partial-joint replacement may be integrated into the revision system, either as a module or component of the revision implant, or if the partial-joint component is "encased" by the revision implant or otherwise used to support the revision implant components. Similarly, well-secured anchors or other components from a "failed implant" may be reused to anchor the revision implant, if desired and available.

Advantages of this disclosure can include, but are not limited to, (i) customization of joint repair, thereby enhancing the efficacy and comfort level for the patient following the repair procedure; (ii) eliminating the need for a surgeon to measure the defect to be repaired intraoperatively in some embodiments; (iii) eliminating the need for a surgeon to shape the material during the implantation procedure; (iv) providing methods of evaluating curvature of the repair material based on implant, bone or tissue images or based on intraoperative probing techniques; (v) providing methods of repairing joints with only minimal or, in some instances, no loss in bone stock; and (vi) improving postoperative joint congruity.

Thus, the methods described herein allow for the design and use of joint repair material that more precisely fits the defect (e.g., site of implantation) and, accordingly, provides improved repair of the joint.

I. Assessment of Joints and Alignment

The methods and compositions described herein can be used to treat defects resulting from disease of the cartilage (e.g., osteoarthritis), bone damage, cartilage damage, trauma, and/or degeneration due to overuse or age. This disclosure allows, among other things, a health practitioner to evaluate and treat such defects. The size, volume and shape of the area of interest can include only the region of cartilage that has the defect, but preferably will also include contiguous parts of the cartilage surrounding the cartilage defect.

As will be appreciated by those of skill in the art, size, curvature and/or thickness measurements can be obtained using any suitable technique. For example, one-dimensional, two-dimensional, and/or three-dimensional measurements can be obtained using suitable mechanical means, laser devices, electromagnetic or optical tracking systems, molds, materials applied to the articular surface that harden and "memorize the surface contour," and/or one or more imaging techniques known in the art. Measurements can be obtained non-invasively and/or intraoperatively (e.g., using a probe or other surgical device). As will be appreciated by those of skill in the art, the thickness of the repair device can vary at any given point depending upon the depth of the damage to the cartilage and/or bone to be corrected at any particular location on an articular surface.

As illustrated in FIG. **1**A, typically the process begins by first obtaining one or more images of a patient's joint that requires revision. This group of images will typically have a series of images of the patient's current joint, which typically includes various images of the "failed" or "failing" implant (i.e., "failed implant" images). If available, the groups of

images will desirably further include other images taken earlier in the treatment progression of the failed joint, including (1) images of the joint and/or implant taken between the time of original implantation and "failure" of the prior implant (i.e., "pre-failure implant" images), (2) images of the joint and/or implant taken at the time of original implantation (i.e., "initial implantation" images), (3) images taken prior to initial implantation of the "failed implant" (i.e., "pre-implant work-up" images), and (4) images taken prior to significant failure of the patient's natural joint (i.e., "healthy joint" images). Various additional image sources useful for this disclosure could include images of the "failed implant", both pre and post-failure (i.e., "implant data"), information or images regarding the types and locations of bone cement and/or bony in-growth structures, and any other anatomical data available regarding the patient, including resection surface information, residual cartilage, osteophytes, osteolysis, and/or information regarding injuries or disease states that may affect joint and/or bone strength in any manner (i.e., osteoporosis, arthritis, etc.). Where such additional image groups are readily available, it may be desirable to include such information in the current image group. Other sources of information could include databases of non-patient individuals (i.e., information from specific or general individuals, including normalized information, from specific or general population groups).

Table 1 provides a non-exhaustive list of various data sources and image characteristics particularly useful in practicing the present invention:

TABLE 1

Exemplary Sources of Imaging Data

Image sources
Current scan of patient's anatomy, including "failed implant" and/or "failed anatomy"
Time-lapse images or 4D images and motion studies of "failed implant"
Contrast enhanced studies of "failed implant"
Historical scans of patient's healthy joint currently requiring revision
Historical scans of patient's joint prior to implantation of "failed implant" (pre-failure)
Scans of patients contra-lateral (opposing) healthy joint
Scans and/or databases of healthy individuals and/or "matched" individuals from general population(s)
Historical scans of "failed implant" after initial implantation but pre-failure
Images and/or data regarding shape, size and features/configuration of "failed implant" (pre-implantation as well as "follow-up" images and image series)
Images and/or data regarding locations of bone cement of other non-biologic structures (i.e., anchors, pins, other implants, etc.)
Images and/or data regarding resection surfaces, unresected surfaces, residual cartilage, osteophytes, osteolysis, bone cement, or other anatomical features prior to implantation of the "failed implant"
Images or data or templates of implant components of "failed implant", either obtained in vivo in the patient or, for example, based on manufacturer's data, in 2D and 3D, including
CAD files or other electronic files

At any point in the various disclosed embodiment, the quality and reliability of various images may be assessed for accuracy, completeness, and are desirably "normalized" to a set standard or standards to facilitate their use during subsequent steps of the disclosed invention. It is desirable that images of poor quality and/or low accuracy will desirably be identified and, if of lesser utility, given a rating of "low confidence" and/or are discarded. In a similar manner, higher quality images and/or those of better accuracy may be given a "higher confidence" rating. If desired, images may be processed and/or enhanced to improve the usefulness of data contained therein, in a known manner.

If desired, the various images in the image group may be evaluated and/or assessed or "cross-referenced" against one another. For example, it may be advantageous to compare, contrast and evaluate the various anatomical image groups over time (i.e., healthy joint, initial implantation, pre-failure implant, and/or failed implant images) to determine disease progression and/or estimate future disease progression. In a similar manner, it may be advantageous to compare, contrast and evaluate the various implant image groups over time (i.e., initial implantation, pre-failure implant, and/or failed implant images) to determine and/or identify implant failure modes (i.e., implant fracture, unacceptable or uneven wear zones, dislocation, modular failures, etc.) or underlying anatomical failure modes (i.e., underlying support structure failure, soft tissue disease, kinematic imbalances, tissue scarification, metastatic disease or infection, etc.).

"Cross-Referencing" of images in the context of the current disclosure contemplates the comparison of one image to another image in the same or a different group of images. Desirably, the "cross-referenced" images will have a common anatomical or other reference feature which facilitates the comparison of features between the relevant images. Cross-referencing can be in 2D and 3D; 2D data can be cross-referenced against 3D data. Historical data can be cross-referenced against current data. Such cross-referencing and comparison can be between images, as well as between individual anatomical features of each image against other anatomical features in the same image and/or against similar features from other images.

In addition, information from one set of images may be utilized in comparison with other images to identify inaccuracies or discrepancies across images and/or among image groups, which may decrease confidence in the accuracy of some images and/or identify additional areas of anatomical concern (i.e., implant fracture and/or dislocation). In a similar manner, information from one set of images may be utilized in comparison with other images to identify consistencies and/or congruencies across images, which may increase confidence in the accuracy of the various images (and/or image components, features or areas of interest) and/or identify anatomical and/or implant areas that remain unchanged or "not of concern" over time. The various accuracies and inaccuracies may be rated and identified in various ways, including through the use of a "heat map" or "color chart" that provides a 2-D, 3-D or 4-D (i.e., time-lapse or other such presentation) rendering of the anatomy and implant, with areas of high confidence in "cool" colors (i.e., blue and green) and areas of low confidence in "hot colors" (i.e., yellow and red) corresponding to various comparison factors, such as (1) significant changes in anatomy, (2) significant changes in implant characteristics and/or alignment, (3) significant perceived inaccuracies across image series, and (4) significant areas or scarification, bone remodeling, etc. Various embodiments may display and/or identify areas of estimated anatomical margins and/or implant location as a "confidence contour map" or other display.

Another advantage for conducting comparisons across image series could include identifying and/or correcting imaging inaccuracies caused or induced by "artifacts" or other factors during the imaging process. For example, metallic "artifacts" (including metallic joint replacement implants) are known to affect the quality of some non-invasive image methods (i.e., x-ray, CT, MRI, etc.) to various degrees, especially where the "location of interest" is adjacent to the artifacts. Not only can such artifacts mask the anatomy near such objects, but such artifacts may cause significant image distortion, which significantly reduces the utility of such imaging in

planning and assessing anatomical structures during revision procedures. If desired, artifact reduction algorithms or other processing steps (including enhancement of low-metal artifact information), as well as imaging techniques desirably "less sensitive" to artifact distortion, may be utilized in an attempt to improve image quality and/or reliability. In addition, the use and comparison of multiple images of the same anatomical region and/or implant, utilizing differing imaging methods (to desirably highlight different types and/or portions of anatomy and/or implant) are contemplated in various embodiments. The use of other images in the image series, including images taken prior to initial implantation of the "artifact," can be used to cross-check the accuracy of such artifact-laden images, and may also be used to correct such distortion where applicable. In a similar manner, data regarding the structure of the "failed implant" may be especially useful in such situations. The external margins of the "failed implant" are often readily discernable on non-invasive images, and knowledge of the internal and peripheral features of the implant (i.e., implant design, shape and size, including bone-facing surfaces of the implant) can be calculated and/or cross-referenced from or against the external margins to estimate the location of corresponding internal surfaces (which are desirably adjacent to estimated margins of the anatomical support structures). Moreover, knowledge of the internal surface location can be used to cross-reference against other images, including against other images of the same implant from differing angles, as well as can be used to identify limits or locations where anatomical structures can or cannot be. I.e., any image that identifies an anatomical structure within a location where the implant exists (i.e., anatomy and implant structure at the same 3-dimensional location) should be either incorrect or may indicate a fractured, dislocated or otherwise displaced implant. Information regarding the thicknesses of implant material at various locations or along various planes may also be useful in evaluating the amount of distortion experienced in a given image or portion of image. Similar implant data can be utilized to determine the thickness of a metal implant along various planes of imaging, and may be utilized to estimate the amount of implant distortion experienced as well as to identify "preferred" imaging angle to reduce or minimize distortion (i.e., choose imaging planes to minimize implant thickness, or to place known planar implant surfaces perpendicular to x-ray imaging, etc).

In one exemplary embodiment, the use of images from a prior scan of the patient, in combination with a current scan of the patient (containing failed implant image(s)) and known data regarding the shape and size of the failed implant (including internal and external surface dimensions) can be processed and/or utilized to provide significant useful data regarding the quality and quantity of anatomical support structure available for use with a revision implant procedure. By knowing the amount of potential anatomical support structure remaining, this embodiment allows the revision implant to be selected and/or designed to require minimum resection and/or preparation of remaining anatomical support structures after implant removal. In addition, if the implant has fractured or otherwise failed in a manner whereby the anatomical support structure has remained substantially intact, a replacement (revision) implant can be chosen or designed that requires little or no alteration to the underlying anatomical support structure prior to implantation. If desired, the bone-facing structures of the revision implant can replicate those of the "failed implant" (to facilitate implantation with little or no cutting or preparation of the underlying anatomical surfaces), while alterations to the joint-facing or articulating structures (and/or the thickness of the implant) can alter the biomechanics of the revision implant and revised joint in a desirable manner.

Another alternate embodiment could utilize the original scans of the patient's anatomy (either prior to or after initial implantation of the primary implant) to create a revision implant and/or surgical tools for use in preparing the anatomical support surfaces for the revision implant. Such devices could include patient-specific anatomical support surfaces for alignment and/or placement of the revision implant. If desired, the original scan data could be normalized, assessed, evaluated and/or corrected as described herein to improve image accuracy and/or quality.

TABLE 2

Exemplary Anatomical and Implant Features

Anatomical Features	Implant Features
Resection surfaces of bone due to primary implant Unresected bone surfaces Residual cartilage Osteophytes Osteolysis Bone Cement Bone density Bone structure	Internal (bone facing) surfaces of the "failed implant" Chamfer cut dimensions and locations of the "failed implant", e.g. based on image data or manufacturer data, in 2D or 3D External (joint facing) surfaces of the "failed implant", e.g. based on image data or manufacturer data, in 2D or 3D Surface corners Peripheral edge(s) Notches Stem shape of the "failed implant", e.g. based on image data or manufacturer data, in 2D or 3D Insert shape, e.g. polyethylene, of the "failed implant, e.g. based on image data (e.g. actual) or manufacturer data (e.g. prior to failure), in 2D or 3D

In a similar manner, the images may be corrected or otherwise evaluated for accuracies relevant to the type and size/thickness of the implant, other artifact, or general or specific known or unknown inaccuracies in the imaging equipment and/or modality. For example, areas of high metal concentration (i.e., thicker sections of an implant) may be more prone to artifact distortion than areas of lesser metal concentration. Similarly, various metal types may be more or less prone to artifact distortion, as will artifacts having low-metal content such as some ceramics and polymers. In addition, the different types of imaging equipment are likely to have different accuracies, not only due to the differing imaging modalities (i.e., 2-D vs. 3D vs. 4D imaging, MRI, CT-scan, CAT, fluoroscopy and x-ray, ultrasound, PET, and/or other radiographic, nuclear, photo-acoustic, thermographic, tomographic and/or ultrasonic imaging techniques, etc.), but also calibration of the related equipment, age of the scans (i.e., older scans may have been held to a lower accuracy standard or may have degraded in storage), and inherent differences in the equipment and/or the various environments of use (i.e., heat, temperature, etc). All of some of these various factors may be included with image data to increase, decrease or otherwise assess the "confidence" of the data accuracy, which may affect how such data is viewed and/or rated during assessment, evaluation, comparison/cross-referencing and/or correction of some of all of the image data. For example, where an older image depicts an anatomical feature that does not correlate to more recent image groups, the older image data may be considered "less reliable" than newer image data, and may be appropriately assessed (i.e., discarded or assigned a low reliability value) or alternatively may be judged to be "more reliable" where the older image was taken without

artifact interference, or by a more reliable imaging modality, etc. Each image or image group (including individual features of interest within an image) may, if desired, be assigned such "reliability ratings," or individual features of images may have differing "reliability ratings", or combinations thereof. The assessment system may also identify common anatomical features across differing image groups, which may affect "reliability ratings" in either a positive or negative manner.

This disclosure contemplates a wide variety of "priority" or "ranking" systems for use with the various assessment and evaluation systems of the present invention. Virtually any combination of priorities can be incorporated into the assessment and evaluation process, typically on a user-defined basis, although the use of pre-defined priorities and/or groups of priorities is also encompassed by this disclosure. For example, higher priorities may be given to data assessed as having a greater "likelihood of accuracy" as defined by the user and/or system. Such greater likelihood could be due to a wide variety of factors, including (1) inherent accuracy of the imaging method, (2) multiple groups of images identifying a common anatomical feature or features (and/or "failed implant" feature or features) in the same or similar location, and/or (3) images where artifacts are absent or have been corrected for. Similarly, the evaluation process can include varying priorities as defined by the user or others, including (1) cost priorities for selecting and/or designing an implant in the most cost-efficient (or least-cost efficient or any variations thereof) manner (i.e., manufacturing costs, material costs, processing/machining costs, use of pre-existing implants versus custom built implants, etc.), (2) scheduling or availability priorities for selecting and/or designing an implant in the time-efficient (or least-time efficient or any variations thereof) manner (i.e., to ensure an implant will be available for use within a specified time frame, etc.), and/or (3) inventory management issues (i.e., to utilize materials and/or implant sizes that are already manufactured and/or are being manufactured in larger quantities, etc).

Once the images have been compared, evaluated, cross-referenced and/or normalized, one or more composite image sets or output sets or generated images may be produced that desirably reflect one or more of the following (1) the most accurate and correct image or set of images of the failed implant, (2) the most accurate and complete image or set of images of the underlying anatomical support structure(s), and/or (3) one or more images or "boundary diagrams" of the anatomical support structures that are estimated to remain after removal of the failed implant. This information may then be used to create revision implants and surgical tools particularized for use in removing the failed implant, revising the supporting anatomical structures, and implanting the revision implant in a desired fashion. Such information may also assist in evaluating and assessing the patient's disease state and/or progression of disease and/or degeneration over a period of time.

If desired, various embodiments may include a graphical user interface (GUI) that allows an operator (surgeon, implant designer, patient, etc.) to conduct pre-operative planning of the revision procedure, including simulating post-operative alignment of the revision implant incorporating augments and/or spacers, wherein the spacer and/or augment can be selected by the user and the alignment information and possible surface information can be modeled, displayed and/or built into (or otherwise incorporated into) the surgical tools and/or surgical implant, including jigs or guides that the jigs include.

In various embodiments, an exterior surface model or "frame diagram" of the failed implant and surrounding anatomical structure of the joint can be created electronically (and/or physically, if desired). In a manner similar to the creation of implants and/or surgical tools and molds described previously in various embodiments of this disclosure, portions of the frame diagram (or physical model) may be utilized to create conforming surfaces for engagement by the surgical tools and molds (i.e., utilizing only surface features of the failed implant, using surface features of the failed implant in combination with anatomical features of the joint surfaces and/or using only anatomical features of the joint surfaces to align the tools and/or molds). Similarly, portions of the frame diagram (or physical model) may be utilized to design and/or select the interior and/or exterior surfaces of the revision implant.

It may also be desirous for an evaluation system to have the capability of evaluating the type and/or size of failed implant in various image sets, including the capability to identify unidentified implants or implant components (and possibly verify the identity of a known or suspected implant type) from a database of known implant designs. In many cases, the exact design, shape and/or size of the failed implant will be unknown, either because surgical records are unavailable, are disorganized or are incorrect, and the use of proper implant information may be important to the evaluation and assessment of various patient information. In various embodiments, the system is desirably capable of evaluation the condition of various implants and/or implant components, facilitating identification of failed or fractured components that may require replacement, while the remaining components may remain in situ, as desired. Once identified, information and/or data regarding the various implant components can be included in the various image/data groups for assessment and/or evaluation and preparation of the revision implant and/or tools. Of course, if information regarding the "failed implant" is already known or is available, such implant information (possibly available based on patient history, surgical reports and/or manufacturer's records) may be included, utilized and/or verified by the evaluation system.

Once the processing, assessment, evaluation and/or cross-referencing/correcting of patient and "failed implant" information has been accomplished to a desired degree, the resulting image and/or data information may be utilized to plan the revision surgery, which can include the creation of revision implants, implant components and surgical tools for preparation of anatomical surfaces and implantation of the revision implant. Revision surgery is particularly well suited to the systems and methods described herein, as the disclosed methods are capable of determining and/or estimating the patient's anatomical structure underlying the "failed implant" to a degree significantly greater than that allowed by current practice. For example, in a typical knee revision procedure, a physician is often unaware of the actual structure and/or condition of the underling margins of the anatomical support structure (i.e., bone and any remaining articular surfaces that may have supported the "failed implant") until the failed implant has been removed in surgery. Because of this, revision implants typically plan and are designed for significant bone removal (to accommodate a "worst case" scenario where most supporting bone has degraded), and often also require an intramedullary stem that serves as an alignment structure for aligning the joint implant, as well as a support structure for securing the implant to the surrounding bone. With the disclosed system, however, a more accurate estimate of the underlying bony support structure can be determined, and thus less bone and other support structures need be removed in preparing for the revision implant, as well as allowing for a revision implant or implant components to be

constructed appropriate to the existing support structure. In addition, the identification of existing support structures, in combination with the use of the failed implant as an anatomical reference point, allows positioning of the revision implant without necessarily resorting to intramedullary or other highly-invasive reference points or methods. Moreover, the present method enables a surgeon to determine, prior to surgery, whether sufficient anatomical support structures remain to support the revision implant without need for an intramedullary stem or other such support structure.

If desired, an appropriate revision implant can be selected from a library or a revision implant can be generated based on the patient specific parameters obtained in the measurements and evaluation. If desired, surgical tools such as custom jigs to assist in the preparation of the anatomical surface can be constructed using information regarding the implant as well as the generated image data. Prior to installing the implant in the joint, the implantation site is prepared and then the implant is installed. One or more of these steps can be repeated as necessary or desired as shown by the optional repeat steps. In various embodiments, the surgical tools of this disclosure can be particularized for use in a patient, for the implantation of a standard joint replacement implant (i.e., a standard or non-patient-specific implant), as desired.

In various embodiments, the resulting image and/or data information may be utilized to create a "custom" revision implant well suited to match and/or conform to the most accurate anatomical data. In various additional embodiments, the resulting data and/or image information may be utilized in combination with "confidence" or "statistical accuracy" data derived by the evaluation software to a degree defined by the user. For example, an implant and/or surgical tool may be specifically designed to have a "95%" confidence that the implant/surgical tool will fit the derived anatomical structure, and would thus be designed such that the internal structural surfaces would accommodate, encompass and/or conform to an anatomical model that follows the estimated contours of the underlying anatomical structures to at least a 95% confidence level. If desired, multiple implants of various confidence levels may be produced for use in a single surgery, with an implant of relatively "lower" confidence value being designed for a patient-specific application for use in a manner similar to a "rescue" revision implant where actual bone conditions significantly different from those estimated, or if the primary revision implant will not accommodate or properly fit the actual anatomical surfaces.

A. Imaging Techniques

I. Thickness and Curvature

As will be appreciated by those of skill in the art, imaging techniques suitable for measuring thickness and/or curvature (e.g., of cartilage and/or bone) or size of areas of diseased cartilage or cartilage loss include the use of x-rays, magnetic resonance imaging (MRI), computed tomography scanning (CT, also known as computerized axial tomography or CAT), optical coherence tomography, ultrasound imaging techniques, optical imaging techniques, and others disclosed herein and/or are well known in the art. (See, also, International Patent Publication WO 02/22014 to Alexander, et al., published Mar. 21, 2002; U.S. Pat. No. 6,373,250 to Tsoref et al., issued Apr. 16, 2002; and Vandeberg et al. (2002) *Radiology* 222:430-436). Contrast or other enhancing agents can be employed using any route of administration, e.g. intravenous, intra-articular, etc.

Based on the imaging performed, and any assessment, evaluation, correction and/or cross-referencing performed as previously described, the software may evaluate the fit of different implants and/or surgical guide templates with regard to dimensions, overall size and shape. The dimensions, overall size and shape may be optimized with regard to cortical bone shape and dimensions, cortical bone thickness, endosteal bone shape, size of marrow cavity, articular surface shape and dimensions, subchondral bone shape and dimensions, or subchondral bone thickness. Thus, for example, an implant may either be custom made or selected from a number of pre-manufactured implants that is optimized with regard to any of the following or combinations thereof: AP dimensions and shape, mediolateral dimensions and shape, superoinferior dimensions and shape, shape of the articulating surface, shape and dimensions of the interface in contact with cortical bone, shape and dimensions of intramedullary portions or components. These parameters may also be optimized for implant function, e.g. for different degrees of joint flexion or extension or abduction or adduction or internal or external rotation.

In certain embodiments, CT or MRI is used to assess tissue, bone, cartilage and any defects therein, for example cartilage lesions or areas of diseased cartilage, to obtain information on subchondral bone or cartilage degeneration and to provide morphologic or biochemical or biomechanical information about the area of damage. Specifically, changes such as fissuring, partial or full thickness cartilage loss, and signal changes within residual cartilage can be detected using one or more of these methods. For discussions of the basic NMR principles and techniques, see MRI Basic Principles and Applications, Second Edition, Mark A. Brown and Richard C. Semelka, Wiley-Liss, Inc. (1999). For a discussion of MRI including conventional T1 and T2-weighted spin-echo imaging, gradient recalled echo (GRE) imaging, magnetization transfer contrast (MTC) imaging, fast spin-echo (FSE) imaging, contrast enhanced imaging, rapid acquisition relaxation enhancement (RARE) imaging, gradient echo acquisition in the steady state (GRASS), and driven equilibrium Fourier transform (DEFT) imaging, to obtain information on cartilage, see Alexander, et al., WO 02/22014. Other techniques include steady state free precision, flexible equilibrium MRI and DESS. Thus, in preferred embodiments, the measurements produced are based on three-dimensional images of the joint obtained as described in Alexander, et al., WO 02/22014 or sets of two-dimensional images ultimately yielding 3D information. Two-dimensional, and three-dimensional images, or maps, of the cartilage alone or in combination with a movement pattern of the joint, e.g. flexion—extension, translation and/or rotation, can be obtained. Three-dimensional images can include information on movement patterns, contact points, contact zone of two or more opposing articular surfaces, and movement of the contact point or zone during joint motion. Two- and three-dimensional images can include information on biochemical composition of the articular cartilage. In addition, imaging techniques can be compared over time, for example to provide up-to-date information on the shape and type of repair material needed.

Traditional CT and MRI scans utilize two dimensional cross-sectional images acquired in different imaging planes to visualize complex three-dimensional articular anatomy. With computed tomography, these slices are typically acquired in the axial plane. The in-plane resolution is typically on the order of 0.25×0.25 millimeters. The slice thickness may vary from one to five millimeters. Thus, the resolution obtained with these imaging studies is not isotropic. Moreover, the CT slices and, similarly with MRI, may be separated by one or more millimeters. This means that the resolution of the images is excellent within the imaging plane. However, two to ten-fold loss in image resolution can be encountered in a plane perpendicular to the slices acquired by

the CT or MRI scanner. This limitation in resolution perpendicular to the imaging plane can result in inaccuracies in deriving the three-dimensional shape of, without limitation, an implant and/or a 3-D guidance template, described in more detail below.

In accordance with one embodiment, spiral CT imaging is utilized to acquire the images rather than standard CT technology. With recent CT technology, slip ring technology is incorporated in the scanner. A slip ring is a circular contact with sliding brushes that allows the gantry to rotate continuously, untethered by electrical wires. The use of slip ring technology eliminates the initial limitations at the end of each slice acquisition. Thus, the rotating gantry is free to rotate continuously throughout the examination of a joint. A slip ring CT scanner design allows greater rotational velocities, thereby shortening scan times. With a spiral CT scan data is acquired while the table is moving. As a result, the x-ray source moves in a spiral or helical rather than a circular pattern around the patient. The speed of the table motion relative to the rotation of the CT gantry is a very important consideration for image quality in helical or spiral CT scanning. This parameter is call pitch. In a preferred embodiment, spiral CT scans will be acquired through the joint wherein these spiral CT scans afford a resolution that is isotropic, for example 1 millimeter by 1 millimeter by 1 millimeter in x, y and z direction, or, more preferred, 0.75×0.75×0.75 millimeters in x, y and z direction, or, more preferred, 0.5×0.5×0.5 millimeters in x, y and z direction, or, more preferred 0.25×0.25×0.25 millimeters in x, y and z direction. Near isotropic data sets are also acceptable particularly if the maximum resolution in any one of the three special orientations does not exceed 1.5 millimeters, or, more preferred 1.0 millimeters, or, more preferred 0.75 millimeters, or, more preferred 0.5 millimeters. Thus, this disclosure recognizes that the accuracy in placing a 3-D guidance template on an articular surface, or shaping an implant, can be greatly improved with isotropic or near isotropic data sets as compared to traditional 2-D slice based data sets derived from either CT or MRI or other imaging technologies. For example, a knee joint scan data acquired with near isotropic resolution of 0.4×0.4×0.7 millimeters (e.g. a resolution ratio of less than 2:1 between the different dimensions and resolution in all three dimensions preferably better than 1 mm) will yield greater positional accuracy in placing a 3-D guidance template on the articular surface than scan data acquired using traditional CT scans, for example, with a scan resolution of 0.4×0.4×1.2 millimeters.

With MRI, standard acquisition call sequences also result in two dimensional slices for displaying complex three dimensional articular anatomy. The two dimensional slices can be acquired using 2-D or 3-D Fourier transformation. After the 2-D or 3-D transform, 2-D slices are available for image viewing and image processing. Of note, typically the image resolution in the imaging plane will be two or more fold greater than the image resolution perpendicular to the primary imaging plane. Similar to CT, this limitation in spatial resolution in the plane perpendicular to the imaging plane can result in inaccuracies in deriving and subsequently placing **3**-D guidance molds. In a preferred embodiment, MRI data is acquired or processed so that the data used for generating the 3-D guidance mold or implant has isotropic or near isotropic resolution. For example, isotropic or near isotropic resolution may be achieved by fusing two non-parallel imaging planes acquired using standard 2-D or 3-D Fourier transform images, registering them relative to each other and performing an image fusion (see U.S. patent application Ser. No. 10/728,731, entitled "Fusion of Multiple Imaging Planes for Isotropic Imaging in MRI and Quantitative Image Analysis using Isotropic or Near-Isotropic Imaging," hereby incorporated by reference in its entirety). Alternatively, using latest generation scan technology, for example, with 3-D FSE, 3-D DESS, 3-D MENSA, 3-D PAVA, 3-D LAVA, 3-D MERGE, 3-D MEDIC imaging sequences, multi-channel coils, high field magnets, advanced gradient technology, isotropic or near isotropic acquisition using 3-D Fourier transform can be obtained. Using such advanced imaging technology, image resolution of 0.5 by 0.5 by 0.8 millimeters or greater may be obtained, achieving near isotropic and even isotropic resolution, with preferably resolution in all three dimensions of less than 1 mm.

As will be appreciated by those of skill in the art, imaging techniques can be combined, if desired. For example, C-arm imaging or x-ray fluoroscopy can be used for motion imaging, while MRI can yield high resolution cartilage information. C-arm imaging can be combined with intra-articular contrast to visualize the cartilage.

Any of the imaging devices described herein can also be used intra-operatively (see, also below), for example using a hand-held ultrasound and/or optical probe to image the articular surface intra-operatively. FIG. **2** illustrates a color reproduction of a three-dimensional thickness map of the articular surface on the distal femur. The dark holes within the cartilage indicate areas of full cartilage loss.

ii. Anatomical and Mechanical Axes, Virtual Ligament Balancing

Imaging can be used to determine the anatomical and biomechanical axes of an extremity associated with a joint, which can then be used in creating an implant or surgical guide template or mold. Suitable tests include, for example, an x-ray, or an x-ray combined with an MRI. Typically, anatomical landmarks are identified on the imaging test results (e.g., the x-ray film) and those landmarks are then utilized to directly or indirectly determine the desired axes. Thus, for example, if surgery is contemplated in a hip joint, knee joint, or ankle joint, an x-ray can be obtained. This x-ray can be a weight-bearing film of the extremity, for example, a full-length leg film taken while the patient is standing. This film can be used to determine the femoral and tibial anatomical axes and to estimate the biomechanical axes. As will be appreciated by those of skill in the art, these processes for identifying, e.g., anatomical and mechanical axis of the joint can be applied to other joints without departing from the scope of the invention. Similarly, the use of processed and/or evaluated images or image groups, as described in various locations herein, can be utilized as an exemplary "imaging" source in for further use in designing, manufacturing and/or choosing appropriate implants, as described in the various embodiments disclosed and discussed herein.

Anatomical and biomechanical axes can also be determined using other imaging modalities, including but not limited to, computed tomography and MRI. For example, a CT scan can be obtained through the hip joint, the knee joint, and the ankle joint. Optionally, the scan can be reformatted in the sagittal, coronal, or other planes. The CT images can then be utilized to identify anatomical landmarks and to determine the anatomical and biomechanical axes of the hip joint, knee joint, and/or ankle joint.

Similarly, an MRI scan can be obtained for this purpose. For example, an MRI scan of the thigh and pelvic region can be obtained using a body coil or a torso phased array coil. A high resolution scan of the knee joint can be obtained using a dedicated extremity coil. A scan of the calf/tibia region and the ankle joint can be obtained again using a body coil or a torso phased array coil. Anatomical landmarks can be iden-

tified in each joint on these scans and the anatomical and biomechanical axes can be estimated using this information.

In various embodiments, the imaging scan can be extended for 5 cm, more preferably 10 cm, or more preferably 15 cm above and/or below the joint thereby deriving anatomic information that can be used to derive the anatomic and mechanical axis. For example, an MRI or CT scan can be obtained through a knee joint. The scan can extend 15 cm above and below the joint. The mid-femoral line and mid-tibial line as well as other anatomic landmarks such as the femoral transepicondylar line or Whiteside line or posterior condylar line can be determined and can be used to estimate the anatomic and biomechanical axes. Thus, in the example of a knee joint, no additional scanning through the hip joint and ankle joints will be needed.

With, for example, MRI, even larger coverage may be obtained, for example with a series of axial, sagittal or coronal slices obtained with a large field of view, e.g. 20 cm or more preferably 25 cm, or more preferably 30 cm, or more preferably 35 cm. These large field of view scans can be utilized to estimate the anatomic and biomechanical axes as described above. They lack, however, information on the surface detail of the joint due to limitations in spatial resolution. A second or additional scan can be performed with high resolution, e.g. with spatial resolution and x and y axis of less than 1.0 mm, or, more preferably, less than 0.8 mm, or, more preferably, less than 0.6 mm. The additional high resolution scan may be utilized to derive the articular surface detail needed for a good and accurate fit between the guidance template or implant, and the articular surface or adjacent structures.

A mechanical axis and, in some instances, an anatomical axis may advantageously be defined by imaging the entire extremity in question, or through imaging combinations and/or assessment, as disclosed herein. Such imaging may include cross-sectional, spiral or volumetric imaging via a CT or MRI scan or optical imaging through the entire extremity, or acquisition of select images or slices or volumes through an area of interest such as a hip joint, a knee joint or ankle joint.

In an illustrative embodiment, scans through the entire or portions of an entire extremity covering multiple joints may be replaced with an extended scan through a single joint such as a knee joint. For example, it may not be sufficient to estimate a mechanical axis or an anatomical access with a standard knee scan such as a CT scan or MRI scan that includes, for example, only ten centimeter of the area or volume of interest above the tibiofemoral joints space. With an extended scan, a larger area adjacent to the target joint can be included in the scan, e.g. fifteen centimeters above and below the medial tibia femoral joint space, twenty centimeters above and below the medial tibia femoral joint space, fifteen centimeters above and twenty centimeters below the medial tibiofemoral joint space, twenty centimeters above and twenty-five centimeters below the medial tibiofemoral joint space. While the extended scan is less involved on the operative side than the scan involving the neighboring joints, it can, optionally be used to provide an estimate of the anatomical axis, mechanical axis, and/or an implant axes or related planes. Thus, better ease of use is provided at the expense of, possibly, more radiation and possibly, less accuracy.

In another embodiment, cross-sectional or volumetric images such as CT scans or MRI scans may be acquired through more than one joint, typically one or more joints neighboring the one contemplated for surgery. For example, CT or MRI slices, CT spirals, CT or MRI volumes, MRI two plane acquisitions with optional image fusion, or other tomographic acquisitions are acquired through the hip joint, knee joint and ankle joint in a patient scheduled for total knee replacement surgery. The 3D surgical guidance templates may be optimized by using anatomic and/or biomechanical information obtained in the adjacent neighboring joints, for example, resulting in an improved anatomic or functional result. By using cross-sectional or volumetric imaging information, more accurate identification of anatomic landmarks for identifying relevant anatomical and/or mechanical axis, relevant planes including surgical planes and implant planes, as well as implant axes can be achieved when compared to x-rays or CT scout scans, in particular when the cross-sectional or volumetric data are acquired through neighboring joints. The accuracy of the position, orientation, shape or combinations thereof, of a 3D guide template can thus be improved with resulting improvement in accuracy of the surgical correction of underlying deformities such as varus, valgus, abduction, adduction, or rotation deformities.

An imaging test obtained during weight-bearing conditions has some inherent advantages, in that it demonstrates normal as well as pathological loading and load distribution. A cross-sectional imaging study such as a CT scan or MRI scan has some advantages because it allows one to visualize and demonstrate the anatomical landmarks in three, rather than two, dimensions, thereby adding accuracy. Moreover, measurements can be performed in other planes, such as the sagittal or oblique planes, that may not be easily accessible in certain anatomical regions using conventional radiography. In principle, any imaging test can be utilized for this purpose.

The mechanical axis can be defined as the axis going from the center of the femoral head, between the condylar surfaces and through the ankle joint The software may automatically, semi-automatically or manually assisted find or identify the relevant anatomic points to calculate the anatomic and biomechanical axes, in accordance with various embodiments of the invention. For example, the software or the user can find the center of the femoral head. Optionally, this can be done in 3D rather than only in 2D. Thus, for example, in the femoral head, the software can find the center of the femoral head relative to its x, y, and z-dimensions. Alternatively, the relevant anatomic points can be selected manually and the axes can be calculated.

In another embodiment the software can compute methods of adjusting varus or valgus or ante- or retroversion deformity or rotational deformity based on such anatomic and mechanical axis measurements. For example, the surface of a surgical guide template can be adapted so that surgical cuts performed for a total knee implant can be placed to correct an underlying varus or valgus deformity or, for example, ante- or retroversion. Alternatively, the openings/cut planes of a surgical guide template used for drilling, cutting and the like can be adjusted to achieve a varus or valgus correction to a near anatomic or physiologic range. These adjustments can be optimized for the implants of different manufacturers, e.g. Johnson & Johnson, Stryker, Smith & Nephew, Biomet and Zimmer.

In various embodiments, gait, loading and other physical activities of a joint as well as static joint positions may be simulated using a computer workstation. The template and its apertures and the resultant surgical templates and/or procedures, e.g. cuts, drilling, rasping, may be optimized using this information to achieve an optimal functional result. For example, the template and its apertures and the resultant implant position may be optimized for different degrees of flexion and extension, internal or external rotation, abduction or adduction, and ante or retroversion. Thus, the templates may be used to achieve motion that is optimized in one, two or

more directions. Not only anatomic, but also functional optimization is possible in this manner.

The origin and insertion of ligaments, e.g. the anterior and posterior cruciate ligaments and the medial and lateral collateral ligaments in the case of a knee, can be visualized on the scan. With MRI, the ligaments are directly visible. If the ligament is torn, the location of the residual fibers at the origin or attachment can be visualized. Different joint positions can then be simulated and changes in ligament length can be determined for different angles of flexion and extension, internal or external rotation, abduction or adduction, and ante or retroversion. These simulations can be performed without but also with the implant in place. Thus, ligament length—and through this presumed tension—can be estimated virtually with any given implant and implant size. Different implants or component(s) can be tested preoperatively on the computer workstation and the implant or component(s) yielding the optimal ligament performance, e.g. minimal change in ligament length, for different joint positions can be determined pre-operatively. Thus, this disclosure provides among others for pre-operative ligament balancing, including but not limited to by directly visualizing the ligaments or fiber remnants.

For example, in one embodiment a loading apparatus may be applied to the patient to simulate weight-bearing while acquiring the CT scan. A non-limiting example of such a loading apparatus has been described by Dynamed with the Dynawell device. Any loading apparatus that can apply axial or other physiologic or near physiologic loading forces on the hip, knee or ankle joints or two or three of them may be used. Other more sophisticated scanning procedures can be used to derive this information without departing from the scope of the invention.

In a preferred embodiment, when imaging a joint of the lower extremity, a standing, weight-bearing x-ray can be obtained to determine the mechanical axis. In the case of a knee or hip joint, for example, a standing, weight-bearing x-ray of the hip joint or the knee joint can be obtained. Alternatively, standing, weight-bearing x-rays can be obtained spanning the entire leg from the hip to the foot. The x-ray can be obtained in the antero-posterior or posterior-anterior projection but also in a lateral projection or principally any other projection that is desired. The user can measure the mechanical axis, for example, by finding the centroid of the femoral head and the centroid of the ankle joint and by connecting these. This measurement can be performed manually, for example, on a x-ray film or electronically, for example, on a digitized or digital image, including with software assistance. The axis measured on the standing, weight-bearing x-ray can be cross referenced with another imaging modality such a CT or MRI scan. For example, a mechanical axis can be determined on a standing x-ray of the leg. The result and data can be cross referenced, for example, by identifying corresponding bony anatomical landmarks to a CT scan or MRI scan. The result and information can then be utilized to determine the optimal shape of a 3-D guidance template. Specifically, the orientation, position, or shape of the template can be influenced based on the measurement of the mechanical axis. Moreover, the position or shape of any blocks attached to said templates or linkages or the position or shape instruments attached to the mold, block or linkages can be influenced by this measurement. Combining the standing, weight-bearing imaging modality with CT scanning or MRI scanning has the principle advantage that the joint is evaluated during physiological loading. CT or MRI alone, typically do not afford assessment in loaded, weight-bearing condition. If desired, other embodiments can use unloaded image data to simulate loaded, weight-bearing conditions of such joint.

As described above, the mechanical axis can be evaluated in different planes or in three dimensions. For example, the actual mechanical axis can be assessed in the AP plane and a desired mechanical axis can be determined in this plane. In addition, the actual mechanical axis can be determined in the lateral plane, for example, in the lateral projection radiograph, and the desired mechanical axis can be determined in the lateral plane. By measuring the relevant biomechanical and anatomical axis in two or more planes, the shape of a 3-D guidance template and/or implant can be further refined and optimized with result in improvements in clinical and patient function.

The biomechanical or anatomical axis may also be measured using other approaches including a non-weight bearing position. For example, anatomical landmarks can be identified on a CT scout scan and cross referenced to a joint such as a knee joint or a hip joint for which surgery is contemplated. Thus, for example, the user can measure and determine the centroid of the ankle joint and the centroid of the hip joint for knee surgery using the CT scout scan.

In a preferred embodiment, the anatomical landmarks are determined using CT slices or MRI slices rather than a scout scan. A CT scout scan or MRI scout scan can have inherent limitations in spatial resolution. A CT scout scan is typically a single, 2-D radiographic image of the extremity lacking 3-D anatomical information and lacking high spatial resolution. An MRI scout scan is typically composed of multiple 2-D MRI slices, possibly acquired in one, two, or three planes. However, the resolution of the MRI scout scan is typically also limited. By acquiring selective slices and even isotropic or near isotropic data sets through neighboring joints, anatomical landmarks can be identified in a more reliable manner thereby improving the accuracy of anatomical and mechanical axis determination. This improvement in accuracy translates into an improvement in accuracy in the resultant 3-D guidance mold, for example, a knee or hip joint, including improved accuracy of its shape, orientation, or position.

Computed Tomography imaging has been shown to be highly accurate for the determination of the relative anatomical and biomechanical axes of the leg (Testi Debora, Zannoni Cinzia, Cappello Angelo and Viceconti Marco. "Border tracing algorithm implementation for the femoral geometry reconstruction." *Comp. Meth. and Programs in Biomed*., Feb. 14, 2000; Farrar M J, Newman R J, Mawhinney R R, King R. "Computed tomography scan scout film for measurement of femoral axis in knee arthroplasty." *J. Arthroplasty.* 1999 December; 14(8): 1030-1; Kim J S, Park T S, Park S B, Kim J S, Kim I Y, Kim S I. "Measurement of femoral neck anteversion in 3D. Part 1: 3D imaging method." *Med. and Biol. Eng. and Computing*. 38(6): 603-609, November 2000; Akagi M, Yamashita E, Nakagawa T, Asano T, Nakamura T. "Relationship between frontal knee alignment and reference axis in the distal femur." *Clin. Ortho. and Related Res*. No. 388, 147-156, 2001; Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Sloten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering." *Med. Eng. and Phys.* 24 (2002) 617-622; Lam Li On, Shakespeare D. "Varus Nalgus alignment of the femoral component in total knee arthroplasty." *The Knee,* 10 (2003) 237-241).

The angles of the anatomical structures of the proximal and distal femur also show a certain variability level (i.e. standard deviation) comparable with the varus or valgus angle or the angle between the anatomical femoral axis and the mechani-

cal axis (Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Sloten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering." *Med. Eng. and Phys.* 24 (2002) 617-622). Thus, a preferred approach for assessing the axes is based on CT scans of the hip, knee and ankle joint or femur rather than only of the knee region.

CT has been shown to be efficient in terms of the contrast of the bone tissue with respect to surrounding anatomical tissue so the bone structures corresponding to the femur and tibia can be extracted very accurately with semi automated computerized systems (Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Sloten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering." *Med. Eng. and Phys.* 24 (2002) 617-622; Testi Debora, Zannoni Cinzia, Cappello Angelo and Viceconti Marco. "Border tracing algorithm implementation for the femoral geometry reconstruction." *Comp. Meth. and Programs in Biomed., Feb.* 14, 2000).

While 2-D CT has been shown to be accurate in the estimation of the mechanical axis (Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez E, Sloten J V, Oris P. "Morphological study of the proximal femur: a new method of geometrical assessment using 3 dimensional reverse engineering." Med. Eng. and Phys. 24 (2002) 617-622; Testi Debora, supra.; Lam Li On, Supra, 3-D CT has been shown to be more accurate for the estimation of the femoral anteversion angle (Kim J S, Park T S, Park S B, Kim J S, Kim I Y, Kim S I. Measurement of femoral neck anteversion in 3D. Part 1: 3D imaging method. Medical and Biological engineering and computing. 38(6): 603-609, November 2000; Kim J S, Park T S, Park S B, Kim J S, Kim I Y, Kim S I. Measurement of femoral neck anteversion in 3D. Part 1: 3D modeling method. Medical and Biological engineering and computing. 38(6): 610-616, November 2000). Farrar used simple CT 2-D scout views to estimate the femoral axis (Farrar M J, Newman R J, Mawhinney R R, King R. Computed tomography scan scout film for measurement of femoral axis in knee arthroplasty. J. Arthroplasty. 1999 December; 14(8): 1030-1).

In one embodiment, 2-D sagittal and coronal reconstructions of CT slice images are used to manually estimate the mechanical axis. One skilled in the art can easily recognize many different ways to automate this process. For example, a CT scan covering at least the hip, knee and ankle region is acquired. This results in image slices (axial) which can be interpolated to generate the sagittal and coronal views.

In addition to the various comparison, evaluation steps disclosed herein, preprocessing (filtering) of the slice images can be used to improve the contrast of the bone regions so that they can be extracted accurately using simple thresholding or a more involved image segmentation tool like LiveWire or active contour models.

Identification of landmarks of interest like the centroid of the tibial shaft, the ankle joint, the intercondylar notch and the centroid of the femoral head can be performed. The mechanical axis can be defined as the line connecting the proximal and the distal centroids, i.e. the femoral head centroid, the tibial or ankle joint centroid. The position of the intercondylar notch can be used for evaluation of possible deviations, errors or deformations including varus and valgus deformity.

In various embodiments, multiple imaging tests can be combined. For example, the anatomical and biomechanical axes can be estimated using a weight-bearing x-ray of the extremity or portions of the extremity. The anatomical information derived in this fashion can then be combined with a CT or MRI scan of one or more joints, such as a hip, knee, or ankle joint. Landmarks seen on radiography can then, for example, be cross-referenced on the CT or MRI scan. Axis measurements performed on radiography can be subsequently applied to the CT or MRI scans or other imaging modalities. Similarly, the information obtained from a CT scan can be compared with that obtained with an MRI or ultrasound scan.

In one embodiment, image fusion of different imaging modalities can be performed. For example, if surgery is contemplated in a knee joint, a full-length weight-bearing x-ray of the lower extremity can be obtained. This can be supplemented by a spiral CT scan, optionally with intra-articular contrast of the knee joint providing high resolution three-dimensional anatomical characterization of the knee anatomy even including the menisci and cartilage. This information, along with the axis information provided by the radiograph can be utilized to select or derive therapies, such as implants or surgical instruments.

In certain embodiments, it may be desirable to characterize the shape and dimension of intra-articular structures, including subchondral bone or the cartilage. This may be done, for example, by using a CT scan, preferably a spiral CT scan of one or more joints. The spiral CT scan can optionally be performed using intra-articular contrast. Alternatively, an MRI scan can be performed. If CT is utilized, a full spiral scan, or a few selected slices, can be obtained through neighboring joints. Typically, a full spiral scan providing full three-dimensional characterization would be obtained in the joint for which therapy is contemplated. If implants, or templates, for surgical instruments are selected or shaped, using this scan, the subchondral bone shape can be accurately determined from the resultant image data. A standard cartilage thickness and, similarly, a standard cartilage loss can be assumed in certain regions of the articular surface. For example, a standard thickness of 2 mm of the articular cartilage can be applied to the subchondral bone in the anterior third of the medial and lateral femoral condyles. Similarly, a standard thickness of 2 mm of the articular cartilage can be applied to the subchondral bone in the posterior third of the medial and lateral femoral condyles. A standard thickness of 0 mm of the articular cartilage can be applied in the central weight-bearing zone of the medial condyle, and a different value can be applied to the lateral condyle. The transition between these zones can be gradual, for example, from 2 mm to 0 mm. These standard values of estimated cartilage thickness and cartilage loss in different regions of the joint can optionally be derived from a reference database. The reference database can include categories such as age, body mass index ("BMI"), severity of disease, pain, severity of varus deformity, severity of valgus deformity, Kellgren-Lawrence score, along with other parameters that are determined to be relative and useful. Use of a standard thickness for the articular cartilage can facilitate the imaging protocols required for pre-operative planning.

Alternatively, however, the articular cartilage can be fully characterized by performing a spiral CT scan of the joint in the presence of intra-articular contrast or by performing an MRI scan using cartilage sensitive pulse sequences.

The techniques described herein can be used to obtain an image of a joint that is stationary, either weight bearing or not, or in motion or combinations thereof. Imaging studies that are obtained during joint motion can be useful for assessing the load bearing surface. This can be advantageous for designing or selecting implants, e.g. for selecting reinforcements in high load areas, for surgical tools and for implant placement, e.g. for optimizing implant alignment relative to high load areas.

iii. Joint Space

In accordance with other embodiments, a method and system for determining joint space width is provided. Without limitation, a CT scan, MRI scan, optical scan, and/or ultrasound imaging is performed. The medial and lateral joint space width in a knee joint, the joint space in a hip joint, ankle joint or other joint is evaluated. This evaluation may be performed in two dimensions, using a single scan plane orientation, such as sagittal or coronal plane, or it may be performed in three dimensions. The evaluation of joint space width may include measuring the distance from the subchondral bone plate of one articular surface to the subchondral bone plate of the opposing articular surface. Alternatively, the cartilage thickness may be measured directly on one or more articular surfaces. Joint space width or cartilage thickness may be measured for different regions of the joint and joint space width and cartilage loss can be evaluated in anterior, posterior, medial, lateral, superior and/or inferior positions. The measurements may be performed for different positions of the joint such as a neutral position, 45 degrees of flexion, 90 degrees of flexion, 5 degrees of abduction, 5 degrees of internal rotation and so forth. For example, in a knee joint, the joint space width may be evaluated in extension and at 25 degrees of knee flexion and 90 degrees of knee flexion. The medial and lateral joint space width may be compared and differences in medial and lateral joint space width can be utilized to optimize the desired postoperative correction in anatomical or mechanical axis alignment based on this information. The shape, orientation, or position of a 3D guided template may be adjusted using this information, for example, in knee or hip implant placement or other surgeries.

For example, the measurement may show reduced joint space width or cartilage thickness in the medial compartment when compared to a normal anatomic reference standard, e.g. from age or sex or gender matched controls, and/or lateral compartment. This can coincide with valgus alignment of the knee joint, measured, for example, on the scout scan of a CT-scan or the localizer scan of an MRI scan including multiple localizer scans through the hip, knee and ankle joints.

If the mechanical axis estimated on the comparison of the medial and lateral joint space width coincides with the mechanical axis of the extremity measured on the scout scan, no further adjustment may be necessary. If the mechanical axis estimated on the comparison of the medial and lateral joint space width does not coincide with the mechanical axis of the extremity measured on the CT or MRI scout scan, additional correction of the valgus deformity (or in other embodiments, varus or other deformities) can be achieved.

This additional correction may be determined, for example, by adding the difference in axis correction desired based on mechanical axis measured by comparison of the medial lateral joint space width and axis correction desired based on measurement of the mechanical axis of the extremity measured on the scout or localizer scan to axis correction desired based on measurement of the mechanical axis of the extremity measured on the scout or localizer scan alone. By combining the information from both, measurement of joint space width of the median and lateral compartment and measurement of the mechanical axis using the scout scan or localizer scan or, for example, a weight bearing x-ray, an improved assessment of axis alignment during load bearing conditions can be obtained with resultant improvements in the shape, orientation or position of the 3D guidance template and related attachments or linkages.

Optionally, the extremity can be loaded while in the scanner, for example, using a compression harness. Examples for compression harnesses have been published, for example, by Dynawell.

iv. Estimation of Cartilage Loss

In another embodiment, an imaging modality such as spiral CT, spiral CT arthography, MRI, optical imaging, optical coherence tomography, ultrasound and others may be used to estimate cartilage loss in one, two or three dimensions. The information can be used to determine a desired correction of a measured biomechanical or anatomical axis. The correction can be in the anterior-posterior, medio-lateral, and/or superior-inferior direction, or any other direction applicable or desirable, or combinations thereof. The information can be combined with other data e.g., from a standing, weight bearing x-ray or CT scout scan, or an MRI localizer scan or a CT scan or MRI scan that includes axial/spiral or other images through the hip, knee and ankle joints. The information can be used to refine the axis correction desired based on, for example, standing x-rays, non-weight bearing x-rays, CT scout scans, MRI localizer scans and the like.

In another embodiment, any axis correction can be performed in a single plane (e.g., the medial-lateral plane), in two planes (e.g., the medial lateral and anterior-posterior planes), or multiple planes, including oblique planes that are biomechanically or anatomically relevant or desirable.

v. High Resolution Imaging

Additional improvements in accuracy of the 3D guide template and/or implants surfaces may be obtained with use of imaging technology that yields high spatial resolution, not only within the imaging plane, but along all three planes, specifically the X, Y and Z axis. With CT scanning, this can be achieved with the advent of spiral CT Scanning techniques. With MRI, dual or more plane scanning or volumetric acquisition can be performed. If dual or more plane MRI scanning is performed, these multiple scan planes can be fused, for example by cross-registration and resampling along the X, Y and Z axis. The resultant effective resolution in X, Y and Z direction is greatly improved as compared to standard CT scanning or standard MRI scanning. Improvements in resolution have the advantage that the resultant 3D guide templates can be substantially more accurate, for example with regard to their position, shape or orientation.

vi. Phantom Scans

Imaging modalities are subject to scan to scan variations, for example, including spatial distortion. In one embodiment, phantom scans may be performed in order to optimize the scan quality, specifically spatial resolution and spatial distortion. A phantom scan can be performed prior to a patient scan, simultaneously with a patient scan or after a patient scan. Using the phantom scan data, it is possible to make adjustments and optimizations of the scanner and, moreover, to perform image post processing to perform corrections, for example, correction of geometric distortions. Thus, if a phantom scan detects certain geometric distortion in the X, Y or Z axis and the amount of distortion is measured on the phantom scan, a correction factor can be included in the data prior to generating a 3D guide template. The resulting 3D guide template is thus more accurate with resulting improvement in intra-operative cross-reference to the anatomic surface and resultant improved accuracy in any surgical intervention such as drilling or cutting.

In another embodiment, a smoothing operation, e.g. using low frequency filtering, can be performed in order to remove any image related artifacts, such as stepping artifacts between adjacent CT or MRI slices. In some applications, the smoothing operation can be helpful in improving the fit between the joint and the template.

B. Intraoperative Measurements

Alternatively, or in addition to, non-invasive imaging techniques described above, measurements of the size of an area

of diseased cartilage or an area of cartilage loss, measurements of cartilage thickness and/or curvature of cartilage or bone can be obtained intraoperatively during arthroscopy or open arthrotomy. Intraoperative measurements can, but need not, involve actual contact with one or more areas of the articular surfaces.

Devices suitable for obtaining intraoperative measurements of cartilage or bone or other articular structures, and to generate a topographical map of the surface include but are not limited to, Placido disks, optical measurements tools and device, optical imaging tools and devices, and laser interferometers, and/or deformable materials or devices. (See, for example, U.S. Pat. No. 6,382,028 to Wooh et al., issued May 7, 2002; U.S. Pat. No. 6,057,927 to Levesque et al., issued May 2, 2000; U.S. Pat. No. 5,523,843 to Yamane et al. issued Jun. 4, 1996; U.S. Pat. No. 5,847,804 to Sarver et al. issued Dec. 8, 1998; and U.S. Pat. No. 5,684,562 to Fujieda, issued Nov. 4, 1997).

Other devices to measure cartilage and subchondral bone intraoperatively include, for example, ultrasound probes. An ultrasound probe, preferably handheld, can be applied to the cartilage and the curvature of the cartilage and/or the subchondral bone can be measured. Moreover, the size of a cartilage defect can be assessed and the thickness of the articular cartilage can be determined. Such ultrasound measurements can be obtained in A-mode, B-mode, or C-mode. If A-mode measurements are obtained, an operator can typically repeat the measurements with several different probe orientations, e.g. mediolateral and anteroposterior, in order to derive a three-dimensional assessment of size, curvature and thickness.

One skilled in the art will easily recognize that different probe designs are possible using the optical, laser interferometry, mechanical and ultrasound probes. The probes are preferably handheld. In certain embodiments, the probes or at least a portion of the probe, typically the portion that is in contact with the tissue, can be sterile. Sterility can be achieved with use of sterile covers, for example similar to those disclosed in WO 99/08598A1 to Lang, published Feb. 25, 1999.

Analysis on the curvature of the articular cartilage or subchondral bone using imaging tests and/or intraoperative measurements can be used to determine the size of an area of diseased cartilage or cartilage loss. For example, the curvature can change abruptly in areas of cartilage loss. Such abrupt or sudden changes in curvature can be used to detect the boundaries of diseased cartilage or cartilage defects.

As described above, measurements can be made while the joint is stationary, either weight bearing or not, or in motion.

II. Repair Materials

A wide variety of materials find use in the practice of the present invention, including, but not limited to, plastics, metals, crystal free metals, ceramics, biological materials (e.g., collagen or other extracellular matrix materials), hydroxyapatite, cells (e.g., stem cells, chondrocyte cells or the like), or combinations thereof. Based on the information (e.g., measurements) obtained regarding the defect and the articular surface and/or the subchondral bone, a repair material can be formed or selected. Further, using one or more of these techniques described herein, a cartilage replacement or regenerating material having a curvature that will fit into a particular cartilage defect, will follow the contour and shape of the articular surface, and will match the thickness of the surrounding cartilage. The repair material can include any combination of materials, and typically include at least one non-pliable material, for example materials that are not easily bent or changed.

A. Metal and Polymeric Repair Materials

Currently, joint repair systems often employ metal and/or polymeric materials including, for example, prostheses which are anchored into the underlying bone (e.g., a femur in the case of a knee prosthesis). See, e.g., U.S. Pat. No. 6,203,576 to Afriat, et al. issued Mar. 20, 2001 and U.S. Pat. No. 6,322,588 to Ogle, et al. issued Nov. 27, 2001, and references cited therein. A wide-variety of metals are useful in the practice of the present invention, and can be selected based on any criteria. For example, material selection can be based on resiliency to impart a desired degree of rigidity. Non-limiting examples of suitable metals include silver, gold, platinum, palladium, iridium, copper, tin, lead, antimony, bismuth, zinc, titanium, cobalt, stainless steel, nickel, iron alloys, cobalt alloys, such as Elgiloy®, a cobalt-chromium-nickel alloy, and MP35N, a nickel-cobalt-chromium-molybdenum alloy, and Nitinol™, a nickel-titanium alloy, aluminum, manganese, iron, tantalum, crystal free metals, such as Liquidmetal® alloys (available from LiquidMetal Technologies, www.liquidmetal.com), other metals that can slowly form polyvalent metal ions, for example to inhibit calcification of implanted substrates in contact with a patient's bodily fluids or tissues, and combinations thereof.

Suitable synthetic polymers include, without limitation, polyamides (e.g., nylon), polyesters, polystyrenes, polyacrylates, vinyl polymers (e.g., polyethylene, polytetrafluoroethylene, polypropylene and polyvinyl chloride), polycarbonates, polyurethanes, poly dimethyl siloxanes, cellulose acetates, polymethyl methacrylates, polyether ether ketones, ethylene vinyl acetates, polysulfones, nitrocelluloses, similar copolymers and mixtures thereof. Bioresorbable synthetic polymers can also be used such as dextran, hydroxyethyl starch, derivatives of gelatin, polyvinylpyrrolidone, polyvinyl alcohol, poly[N-(2-hydroxypropyl)methacrylamide], poly(hydroxy acids), poly(epsilon-caprolactone), polylactic acid, polyglycolic acid, poly(dimethyl glycolic acid), poly (hydroxy butyrate), and similar copolymers can also be used.

Other materials would also be appropriate, for example, the polyketone known as polyetheretherketone (PEEK™). This includes the material PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. (Victrex is located at www.matweb.com or see Boedeker www.boedeker.com). Other sources of this material include Gharda located in Panoli, India (www.ghardapolymers.com).

It should be noted that the material selected can also be filled. For example, other grades of PEEK are also available and contemplated, such as 30% glass-filled or 30% carbon filled, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that portion which is unfilled. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon filled PEEK offers wear resistance and load carrying capability.

As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable have very low moisture absorption, and good wear and/or abrasion resistance, can be used without departing from the scope of the invention. The implant can also be comprised of polyetherketoneketone (PEKK).

Other materials that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and generally a pol-

yaryletheretherketone. Further other polyketones can be used as well as other thermoplastics.

Reference to appropriate polymers that can be used for the implant can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated Jan. 10, 2002 and entitled Bio-Compatible Polymeric Materials; PCT Publication WO 02/00275 A1, dated Jan. 3, 2002 and entitled Bio-Compatible Polymeric Materials; and PCT Publication WO 02/00270 A1, dated Jan. 3, 2002 and entitled Bio-Compatible Polymeric Materials.

The polymers can be prepared by any of a variety of approaches including conventional polymer processing methods. Preferred approaches include, for example, injection molding, which is suitable for the production of polymer components with significant structural features, and rapid prototyping approaches, such as reaction injection molding and stereo-lithography. The substrate can be textured or made porous by either physical abrasion or chemical alteration to facilitate incorporation of the metal coating. Other processes are also appropriate, such as extrusion, injection, compression molding and/or machining techniques. Typically, the polymer is chosen for its physical and mechanical properties and is suitable for carrying and spreading the physical load between the joint surfaces.

More than one metal and/or polymer can be used in combination with each other. For example, one or more metal-containing substrates can be coated with polymers in one or more regions or, alternatively, one or more polymer-containing substrate can be coated in one or more regions with one or more metals.

The system or prosthesis can be porous or porous coated. The porous surface components can be made of various materials including metals, ceramics, and polymers. These surface components can, in turn, be secured by various means to a multitude of structural cores formed of various metals. Suitable porous coatings include, but are not limited to, metal, ceramic, polymeric (e.g., biologically neutral elastomers such as silicone rubber, polyethylene terephthalate and/or combinations thereof) or combinations thereof. See, e.g., U.S. Pat. No. 3,605,123 to Hahn, issued Sep. 20, 1971. U.S. Pat. No. 3,808,606 to Tronzo issued May 7, 1974 and U.S. Pat. No. 3,843,975 to Tronzo issued Oct. 29, 1974; U.S. Pat. No. 3,314,420 to Smith issued Apr. 18, 1967; U.S. Pat. No. 3,987,499 to Scharbach issued Oct. 26, 1976; and German Offenlegungsschrift 2,306,552. There can be more than one coating layer and the layers can have the same or different porosities. See, e.g., U.S. Pat. No. 3,938,198 to Kahn, et al., issued Feb. 17, 1976.

The coating can be applied by surrounding a core with powdered polymer and heating until cured to form a coating with an internal network of interconnected pores. The tortuosity of the pores (e.g., a measure of length to diameter of the paths through the pores) can be important in evaluating the probable success of such a coating in use on a prosthetic device. See, also, U.S. Pat. No. 4,213,816 to Morris issued Jul. 22, 1980. The porous coating can be applied in the form of a powder and the article as a whole subjected to an elevated temperature that bonds the powder to the substrate. Selection of suitable polymers and/or powder coatings can be determined in view of the teachings and references cited herein, for example based on the melt index of each.

B. Biological Repair Material

Repair materials can also include one or more biological material either alone or in combination with non-biological materials. For example, any base material can be designed or shaped and suitable cartilage replacement or regenerating material(s) such as fetal cartilage cells can be applied to be the base. The cells can be then be grown in conjunction with the base until the thickness (and/or curvature) of the cartilage surrounding the cartilage defect has been reached. Conditions for growing cells (e.g., chondrocytes) on various substrates in culture, ex vivo and in vivo are described, for example, in U.S. Pat. No. 5,478,739 to Slivka et al. issued Dec. 26, 1995; U.S. Pat. No. 5,842,477 to Naughton et al. issued Dec. 1, 1998; U.S. Pat. No. 6,283,980 to Vibe-Hansen et al., issued Sep. 4, 2001, and U.S. Pat. No. 6,365,405 to Salzmann et al. issued Apr. 2, 2002. Non-limiting examples of suitable substrates include plastic, tissue scaffold, a bone replacement material (e.g., a hydroxyapatite, a bioresorbable material), or any other material suitable for growing a cartilage replacement or regenerating material on it.

Biological polymers can be naturally occurring or produced in vitro by fermentation and the like. Suitable biological polymers include, without limitation, collagen, elastin, silk, keratin, gelatin, polyamino acids, cat gut sutures, polysaccharides (e.g., cellulose and starch) and mixtures thereof. Biological polymers can be bioresorbable.

Biological materials used in the methods described herein can be autografts (from the same subject); allografts (from another individual of the same species) and/or xenografts (from another species). See, also, International Patent Publications WO 02/22014 to Alexander et al. published Mar. 21, 2002 and WO 97/27885 to Lee published Aug. 7, 1997. In certain embodiments autologous materials are preferred, as they can carry a reduced risk of immunological complications to the host, including re-absorption of the materials, inflammation and/or scarring of the tissues surrounding the implant site.

In one embodiment, a probe is used to harvest tissue from a donor site and to prepare a recipient site. The donor site can be located in a xenograft, an allograft or an autograft. The probe is used to achieve a good anatomic match between the donor tissue sample and the recipient site. The probe is specifically designed to achieve a seamless or near seamless match between the donor tissue sample and the recipient site. The probe can, for example, be cylindrical. The distal end of the probe is typically sharp in order to facilitate tissue penetration. Additionally, the distal end of the probe is typically hollow in order to accept the tissue. The probe can have an edge at a defined distance from its distal end, e.g. at 1 cm distance from the distal end and the edge can be used to achieve a defined depth of tissue penetration for harvesting. The edge can be external or can be inside the hollow portion of the probe. For example, an orthopedic surgeon can take the probe and advance it with physical pressure into the cartilage, the subchondral bone and the underlying marrow in the case of a joint such as a knee joint. The surgeon can advance the probe until the external or internal edge reaches the cartilage surface. At that point, the edge will prevent further tissue penetration thereby achieving a constant and reproducible tissue penetration. The distal end of the probe can include one or more blades, saw-like structures, or tissue cutting mechanism. For example, the distal end of the probe can include an iris-like mechanism consisting of several small blades. The blade or blades can be moved using a manual, motorized or electrical mechanism thereby cutting through the tissue and separating the tissue sample from the underlying tissue. Typically, this will be repeated in the donor and the recipient. In the case of an iris-shaped blade mechanism, the individual blades can be moved so as to close the iris thereby separating the tissue sample from the donor site.

In another embodiment, a laser device or a radiofrequency device can be integrated inside the distal end of the probe. The

laser device or the radiofrequency device can be used to cut through the tissue and to separate the tissue sample from the underlying tissue.

In one embodiment, the same probe can be used in the donor and in the recipient. In another embodiment, similarly shaped probes of slightly different physical dimensions can be used. For example, the probe used in the recipient can be slightly smaller than that used in the donor thereby achieving a tight fit between the tissue sample or tissue transplant and the recipient site. The probe used in the recipient can also be slightly shorter than that used in the donor thereby correcting for any tissue lost during the separation or cutting of the tissue sample from the underlying tissue in the donor material.

Any biological repair material can be sterilized to inactivate biological contaminants such as bacteria, viruses, yeasts, molds, mycoplasmas and parasites. Sterilization can be performed using any suitable technique, for example radiation, such as gamma radiation.

Any of the biological materials described herein can be harvested with use of a robotic device. The robotic device can use information from an electronic image for tissue harvesting.

In certain embodiments, the cartilage replacement material has a particular biochemical composition. For instance, the biochemical composition of the cartilage surrounding a defect can be assessed by taking tissue samples and chemical analysis or by imaging techniques. For example, WO 02/22014 to Alexander describes the use of gadolinium for imaging of articular cartilage to monitor glycosaminoglycan content within the cartilage. The cartilage replacement or regenerating material can then be made or cultured in a manner, to achieve a biochemical composition similar to that of the cartilage surrounding the implantation site. The culture conditions used to achieve the desired biochemical compositions can include, for example, varying concentrations. Biochemical composition of the cartilage replacement or regenerating material can, for example, be influenced by controlling concentrations and exposure times of certain nutrients and growth factors.

III. Devices Design

A. Cartilage Models

Using information on thickness and curvature of the cartilage, a physical model of the surfaces of the articular cartilage and of the underlying bone can be created. This physical model can be representative of a limited area within the joint or it can encompass the entire joint. For example, in the knee joint, the physical model can encompass only the medial or lateral femoral condyle, both femoral condyles and the notch region, the medial tibial plateau, the lateral tibial plateau, the entire tibial plateau, the medial patella, the lateral patella, the entire patella or the entire joint. The location of a diseased area of cartilage can be determined, for example using a 3D coordinate system or a 3D Euclidian distance as described in WO 02/22014.

In this way, the size of the defect to be repaired can be determined. As will be apparent, some, but not all, defects will include less than the entire cartilage. Thus, in one embodiment, the thickness of the normal or only mildly diseased cartilage surrounding one or more cartilage defects is measured. This thickness measurement can be obtained at a single point or, preferably, at multiple points, for example 2 point, 4-6 points, 7-10 points, more than 10 points or over the length of the entire remaining cartilage. Furthermore, once the size of the defect is determined, an appropriate therapy (e.g., articular repair system) can be selected such that as much as possible of the healthy, surrounding tissue is preserved.

In other embodiments, the curvature of the articular surface can be measured to design and/or shape the repair material. Further, both the thickness of the remaining cartilage and the curvature of the articular surface can be measured to design and/or shape the repair material. Alternatively, the curvature of the subchondral bone can be measured and the resultant measurement(s) can be used to either select or shape a cartilage replacement material. For example, the contour of the subchondral bone can be used to re-create a virtual cartilage surface: the margins of an area of diseased cartilage can be identified. The subchondral bone shape in the diseased areas can be measured. A virtual contour can then be created by copying the subchondral bone surface into the cartilage surface, whereby the copy of the subchondral bone surface connects the margins of the area of diseased cartilage.

Turning now to FIGS. **2**A-H, various stages of knee resurfacing steps are shown. FIG. **2**A illustrates an example of normal thickness cartilage **700** in the anterior, central and posterior portion of a femoral condyle **702** with a cartilage defect **705** in the posterior portion of the femoral condyle. FIG. **2**B shows the detection of a sudden change in thickness indicating the margins of a cartilage defect **710** that would be observed using the imaging techniques or the mechanical, optical, laser or ultrasound techniques described above. FIG. **2**C shows the margins of a weight-bearing surface **715** mapped onto the articular cartilage **700**. Cartilage defect **705** is located within the weight-bearing surface **715**.

FIG. **2**D shows an intended implantation site (stippled line) **720** and cartilage defect **705**. In this depiction, the implantation site **720** is slightly larger than the area of diseased cartilage **705**. FIG. **2**E depicts placement of a single component articular surface repair system **725**. The external surface of the articular surface repair system **726** has a curvature that seamlessly extends from the surrounding cartilage **700** resulting in good postoperative alignment between the surrounding normal cartilage **700** and the articular surface repair system **725**.

FIG. **2**F shows an exemplary multi-component articular surface repair system **730**. The distal surface **733** of the second component **732** has a curvature that extends from that of the adjacent subchondral bone **735**. The first component **736** has a thickness t and surface curvature **738** that extends from the surrounding normal cartilage **700**. In this embodiment, the second component **732** could be formed from a material with a Shore or Rockwell hardness that is greater than the material forming the first component **736**, if desired. Thus it is contemplated that the second component **732** having at least portion of the component in communication with the bone of the joint is harder than the first component **736** which extends from the typically naturally softer cartilage material. Other configurations, of course, are possible without departing from the scope of the invention.

By providing a softer first component **736** and a firmer second component **732**, the overall implant can be configured so that its relative hardness is analogous to that of the bone-cartilage or bone-meniscus area that it abuts. Thus, the softer material first component **736**, being formed of a softer material, could perform the cushioning function of the nearby meniscus or cartilage.

FIG. **2**G shows another single component articular surface repair system **740** with a peripheral margin **745** which is configured so that it is substantially non-perpendicular to the surrounding or adjacent normal cartilage **700**. FIG. **2**H shows a multi-component articular surface repair system **750** with a first component **751** and a second component **752** similar to that shown in FIG. **2**G with a peripheral margin **745** of the

second component **745** substantially non-perpendicular to the surrounding or adjacent normal cartilage **700**.

Now turning to FIGS. **3**A-E, these figures depict exemplary knee imaging and resurfacing processes. FIG. **3**A depicts a magnified view of an area of diseased cartilage **805** demonstrating decreased cartilage thickness when compared to the surrounding normal cartilage **800**. The margins **810** of the defect have been determined. FIG. **3**B depicts the measurement of cartilage thickness **815** adjacent to the defect **805**. FIG. **3**C depicts the placement of a multi-component mini-prosthesis **824** for articular resurfacing. The thickness **820** of the first component **823** closely approximates that of the adjacent normal cartilage **800**. The thickness can vary in different regions of the prosthesis. The curvature of the distal portion **824** of the first component **823** closely approximates an extension of the normal cartilage **800** surrounding the defect. The curvature of the distal portion **826** of the second component **825** is a projection of the surface **827** of the adjacent subchondral bone **830** and can have a curvature that is the same, or substantially similar, to all or part of the surrounding subchondral bone.

FIG. **3**D is a schematic depicting placement of a single component mini-prosthesis **840** utilizing anchoring stems **845**. As will be appreciated by those of skill in the art, a variety of configurations, including stems, posts, and nubs can be employed. Additionally, the component is depicted such that its internal surface **829** is located within the subchondral bone **830**. In an alternative construction, the interior surface **829** conforms to the surface of the subchondral bone **831**.

FIG. **3**E depicts placement of a single component mini-prosthesis **840** utilizing anchoring stems **845** and an opening at the external surface **850** for injection of bone cement **855** or other suitable material. The injection material **855** can freely extravasate into the adjacent bone and marrow space from several openings at the undersurface of the mini-prosthesis **860** thereby anchoring the mini-prosthesis.

FIGS. **4**A-C, depict an alternative knee resurfacing device. FIG. **4**A depicts a normal thickness cartilage in the anterior, central and posterior portion of a femoral condyle **900** and a large area of diseased cartilage **905** toward the posterior portion of the femoral condyle. FIG. **4**B depicts placement of a single component articular surface repair system **910**. Again, the implantation site has been prepared with a single cut **921**, as illustrated. However, as will be appreciated by those of skill in the art, the repair system can be perpendicular to the adjacent normal cartilage **900** without departing from the scope of the invention. The articular surface repair system is not perpendicular to the adjacent normal cartilage **900**. FIG. **4**C depicts a multi-component articular surface repair system **920**. Again, the implantation site has been prepared with a single cut (cut line shown as **921**). The second component **930** has a curvature similar to the extended surface **930** adjacent subchondral bone **935**. The first component **940** has a curvature that extends from the adjacent cartilage **900**.

C. Customized Containers

In another embodiment, a container or well can be formed to the selected specifications, for example to match the material needed for a particular subject or to create a stock of repair materials in a variety of sizes. The size and shape of the container can be designed using the thickness and curvature information obtained from the joint and from the cartilage defect. More specifically, the inside of the container can be shaped to follow any selected measurements, for example as obtained from the cartilage defect(s) of a particular subject. The container can be filled with a cartilage replacement or regenerating material, for example, collagen-containing materials, plastics, bioresorbable materials and/or any suitable tissue scaffold. The cartilage regenerating or replacement material can also consist of a suspension of stem cells or fetal or immature or mature cartilage cells that subsequently develop to more mature cartilage inside the container. Further, development and/or differentiation can be enhanced with use of certain tissue nutrients and growth factors.

The material is allowed to harden and/or grow inside the container until the material has the desired traits, for example, thickness, elasticity, hardness, biochemical composition, etc. Molds can be generated using any suitable technique, for example computer devices and automation, e.g. computer assisted design (CAD) and, for example, computer assisted modeling (CAM). Because the resulting material generally follows the contour of the inside of the container it will better fit the defect itself and facilitate integration.

D. Designs Encompassing Multiple Component Repair Materials

The articular repair system or implants described herein can include one or more components.

FIGS. **5**A-B shows single and multiple component devices. FIG. **5**A illustrates an example of a single component articular surface repair system **1400** with varying curvature and radii that fits within the subchondral bone **1420** such that the interior surface **1402** of the system **1400** does not form an extension of the surface of the subchondral bone **1422**. The articular surface repair system is chosen to include convex **1402** and concave **1404** portions. Such devices can be preferable in a lateral femoral condyle or small joints such as the elbow joint. FIG. **5**B depicts a multi-component articular surface repair system with a second component **1410** with a surface **1412** that forms an extension of the surface **1422** of the subchondral bone **1420** and a first component **1405** with an interior surface **1406** that forms an extension of the curvature and shape of the surrounding normal cartilage **1415**. The second component **1410** and the first component **1405** demonstrate varying curvatures and radii with convex and concave portions that correspond to the curvature of the subchondral bone **1420** and/or the normal cartilage **1415**. As will be appreciated by those of skill in the art, these two components can be formed such that the parts are integrally formed with each other, or can be formed such that each part abuts the other. Additionally, the relationship between the parts can be by any suitable mechanism including adhesives and mechanical means.

FIGS. **6**A-B show articular repair systems **100** having an outer contour **102** forming an extension of the surrounding normal cartilage **200**. The systems are implanted into the underlying bone **300** using one or more pegs **150**, **175**. The pegs, pins, or screws can be porous-coated and can have flanges **125** as shown in FIG. **5**B.

FIG. **7** shows an exemplary articular repair device **500** including a flat surface **510** to control depth and prevent toggle; an exterior surface **515** having the contour of normal cartilage; flanges **517** to prevent rotation and control toggle; a groove **520** to facilitate tissue in-growth.

FIGS. **8**A-D depict, in cross-section, another example of an implant **640** with multiple anchoring pegs, stems, or screws **645**. FIG. **8**B-D show various cross-sectional representations of various possible embodiments of the pegs, or anchoring stems. FIG. **8**B shows a peg **645** having a notch **646** or groove around its circumference; FIG. **8**C shows a peg **645** with radially-extending arms **647** that help anchor the device in the underlying bone; and FIG. **8**D shows a peg **645** with multiple grooves or flanges **648**.

FIGS. **9**A-B depict an overhead view of an exemplary implant **650** with multiple anchoring pegs **655** which illus-

trates that the pegs are not necessarily linearly aligned along the longitudinal axis of the device.

FIG. **10**A depicts an implant **660** with a peg **661** having radially extending arms **665**. FIGS. **10**B-E are top views of the implant pegs illustrating a variety of suitable alternative shapes.

Examples of one-component systems include, but are not limited to, a plastic, a polymer, a metal, a metal alloy, crystal free metals, a biologic material or combinations thereof. In certain embodiments, the surface of the repair system facing the underlying bone can be smooth. In other embodiments, the surface of the repair system facing the underlying bone can be porous or porous-coated. In another aspect, the surface of the repair system facing the underlying bone is designed with one or more grooves, for example to facilitate the in-growth of the surrounding tissue. The external surface of the device can have a step-like design, which can be advantageous for altering biomechanical stresses. Optionally, flanges can also be added at one or more positions on the device (e.g., to prevent the repair system from rotating, to control toggle and/or prevent settling into the marrow cavity). The flanges can be part of a conical or a cylindrical design. A portion or all of the repair system facing the underlying bone can also be flat which can help to control depth of the implant and to prevent toggle.

Non-limiting examples of multiple-component systems include combinations of metal, plastic, metal alloys, crystal free metals, and one or more biological materials. One or more components of the articular surface repair system can be composed of a biologic material (e.g. a tissue scaffold with cells such as cartilage cells or stem cells alone or seeded within a substrate such as a bioresorable material or a tissue scaffold, allograft, autograft or combinations thereof) and/or a non-biological material (e.g., polyethylene or a chromium alloy such as chromium cobalt).

One or more regions of the articular surface repair system (e.g., the outer margin of the first portion and/or the second portion) can be bioresorbable, for example to allow the interface between the articular surface repair system and the patient's normal cartilage, over time, to be filled in with hyaline or fibrocartilage. Similarly, one or more regions (e.g., the outer margin of the first portion of the articular surface repair system and/or the second portion) can be porous. The degree of porosity can change throughout the porous region, linearly or non-linearly, for where the degree of porosity will typically decrease towards the center of the articular surface repair system. The pores can be designed for in-growth of cartilage cells, cartilage matrix, and connective tissue thereby achieving a smooth interface between the articular surface repair system and the surrounding cartilage.

The repair system (e.g., the second component in multiple component systems) can be attached to the patient's bone with use of a cement-like material such as methylmethacrylate, injectable hydroxy- or calcium-apatite materials and the like.

In certain embodiments, one or more portions of the articular surface repair system can be pliable or liquid or deformable at the time of implantation and can harden later. Hardening can occur, for example, within 1 second to 2 hours (or any time period therebetween), preferably with in 1 second to 30 minutes (or any time period therebetween), more preferably between 1 second and 10 minutes (or any time period therebetween).

One or more components of the articular surface repair system can be adapted to receive injections. For example, the external surface of the articular surface repair system can have one or more openings therein. The openings can be sized to receive screws, tubing, needles or other devices which can be inserted and advanced to the desired depth, for example, through the articular surface repair system into the marrow space. Injectables such as methylmethacrylate and injectable hydroxy- or calcium-apatite materials can then be introduced through the opening (or tubing inserted therethrough) into the marrow space thereby bonding the articular surface repair system with the marrow space. Similarly, screws or pins, or other anchoring mechanisms, can be inserted into the openings and advanced to the underlying subchondral bone and the bone marrow or epiphysis to achieve fixation of the articular surface repair system to the bone. Portions or all components of the screw or pin can be bioresorbable, for example, the distal portion of a screw that protrudes into the marrow space can be bioresorbable. During the initial period after the surgery, the screw can provide the primary fixation of the articular surface repair system. Subsequently, ingrowth of bone into a porous coated area along the undersurface of the articular cartilage repair system can take over as the primary stabilizer of the articular surface repair system against the bone.

The articular surface repair system can be anchored to the patient's bone with use of a pin or screw or other attachment mechanism. The attachment mechanism can be bioresorbable. The screw or pin or attachment mechanism can be inserted and advanced towards the articular surface repair system from a non-cartilage covered portion of the bone or from a non-weight-bearing surface of the joint. The anchoring component (e.g., pegs, pins) can have a porous structure or porous coating to facilitate bone in-growth. For example, a peg or pin can have a porous structure through its cross-sectional diameter, such that it can be readily sawed through when desired, e.g., removing an existing implant in a patient to prepare for a revision surgery.

The interface between the articular surface repair system and the surrounding normal cartilage can be at an angle, for example oriented at an angle of 90 degrees relative to the underlying subchondral bone. Suitable angles can be determined in view of the teachings herein, and in certain cases, non-90 degree angles can have advantages with regard to load distribution along the interface between the articular surface repair system and the surrounding normal cartilage.

The interface between the articular surface repair system and the surrounding normal cartilage and/or bone can be covered with a pharmaceutical or bioactive agent, for example a material that stimulates the biological integration of the repair system into the normal cartilage and/or bone. The surface area of the interface can be irregular, for example, to increase exposure of the interface to pharmaceutical or bioactive agents.

E. Pre-Existing Repair Systems

As described herein, repair systems, including surgical instruments, templates, guides and/or molds, of various sizes, curvatures and thicknesses can be derived, designed or otherwise obtained. These repair systems, including surgical instruments, guides, templates and/or molds, can be catalogued and stored to create a library of systems from which an appropriate system for an individual patient can then be selected. In other words, a defect, or an articular surface, is assessed in a particular subject and a pre-existing repair system, including surgical instruments, templates, guides and/or molds, having a suitable shape and size is selected from the library for further manipulation (e.g., shaping) and implantation.

F. Mini-Prosthesis

As noted above, the methods and compositions described herein can be used to replace only a portion of the articular

surface, for example, an area of diseased cartilage or lost cartilage on the articular surface. In these systems, the articular surface repair system can be designed to replace only the area of diseased or lost cartilage or it can extend beyond the area of diseased or lost cartilage, e.g., 3 or 5 mm into normal adjacent cartilage. In certain embodiments, the prosthesis replaces less than about 70% to 80% (or any value therebetween) of the articular surface (e.g., any given articular surface such as a single femoral condyle, etc.), preferably, less than about 50% to 70% (or any value therebetween), more preferably, less than about 30% to 50% (or any value therebetween), more preferably less than about 20% to 30% (or any value therebetween), even more preferably less than about 20% of the articular surface.

The prosthesis can include multiple components, for example a component that is implanted into the bone (e.g., a metallic device) attached to a component that is shaped to cover the defect of the cartilage overlaying the bone. Additional components, for example intermediate plates, meniscal repair systems and the like can also be included. It is contemplated that each component replaces less than all of the corresponding articular surface. However, each component need not replace the same portion of the articular surface. In other words, the prosthesis can have a bone-implanted component that replaces less than 30% of the bone and a cartilage component that replaces 60% of the cartilage. The prosthesis can include any combination, provided each component replaces less than the entire articular surface.

The articular surface repair system can be formed or selected so that it will achieve a near anatomic fit or match with the surrounding or adjacent cartilage. Typically, the articular surface repair system is formed and/or selected so that its outer margin located at the external surface will be aligned with the surrounding or adjacent cartilage.

Thus, the articular repair system can be designed to replace the weight-bearing portion (or more or less than the weight bearing portion) of an articular surface, for example in a femoral condyle. The weight-bearing surface refers to the contact area between two opposing articular surfaces during activities of normal daily living (e.g., normal gait). At least one or more weight-bearing portions can be replaced in this manner, e.g., on a femoral condyle and on a tibia.

In other embodiments, an area of diseased cartilage or cartilage loss can be identified in a weight-bearing area and only a portion of the weight-bearing area, specifically the portion containing the diseased cartilage or area of cartilage loss, can be replaced with an articular surface repair system.

In another embodiment, the articular repair system can be designed or selected to replace substantially all of the articular surface, e.g. a condyle.

In another embodiment, for example, in patients with diffuse cartilage loss, the articular repair system can be designed to replace an area slightly larger than the weight-bearing surface.

In certain aspects, the defect to be repaired is located only on one articular surface, typically the most diseased surface. For example, in a patient with severe cartilage loss in the medial femoral condyle but less severe disease in the tibia, the articular surface repair system can only be applied to the medial femoral condyle. Preferably, in any methods described herein, the articular surface repair system is designed to achieve an exact or a near anatomic fit with the adjacent normal cartilage.

In other embodiments, more than one articular surface can be repaired. The area(s) of repair will be typically limited to areas of diseased cartilage or cartilage loss or areas slightly greater than the area of diseased cartilage or cartilage loss within the weight-bearing surface(s).

The implant and/or the implant site can be sculpted to achieve a near anatomic alignment between the implant and the implant site. In another embodiment, an electronic image is used to measure the thickness, curvature, or shape of the articular cartilage or the subchondral bone, and/or the size of a defect, and an articular surface repair system is selected using this information. The articular surface repair system can be inserted arthroscopically. The articular surface repair system can have a single radius. More typically, however, the articular surface repair system has varying curvatures and radii within the same plane, e.g. anteroposterior or mediolateral or superoinferior or oblique planes, or within multiple planes. In this manner, the articular surface repair system can be shaped to achieve a near anatomic alignment between the implant and the implant site. This design allows not only allows for different degrees of convexity or concavity, but also for concave portions within a predominantly convex shape or vice versa.

In another embodiment the articular surface repair system has an anchoring stem, used to anchor the device, for example, as described in U.S. Pat. No. 6,224,632 to Pappas et al issued May 1, 2001. The stem, or peg, can have different shapes including conical, rectangular, fin among others. The mating bone cavity is typically similarly shaped as the corresponding stem.

As shown in FIG. **6**, discussed above, the articular surface repair system **100** can be affixed to the subchondral bone **300**, with one or more stems, or pegs, **150** extending through the subchondral plate into the marrow space. In certain instances, this design can reduce the likelihood that the implant will settle deeper into the joint over time by resting portions of the implant against the subchondral bone. The stems, or pegs, can be of any shape suitable to perform the function of anchoring the device to the bone. For example, the pegs can be cylindrical or conical. Optionally, the stems, or pegs, can further include notches or openings or other porous structures to allow bone in-growth. In addition, the stems can be porous coated for bone in-growth. The anchoring mechanisms such as stems or pegs with porous structures can be readily sawed through when desired, e.g., removing an existing implant in a patient to prepare for a revision surgery.

The anchoring stems or pegs can be affixed to the bone using bone cement. An additional anchoring device can also be affixed to the stem or peg. The anchoring device can have an umbrella shape (e.g., radially expanding elements) with the wider portion pointing towards the subchondral bone and away from the peg. The anchoring device can be advantageous for providing immediate fixation of the implant. The undersurface of the articular repair system facing the subchondral bone can be textured or rough thereby increasing the contact surface between the articular repair system and the subchondral bone. Alternatively, the undersurface of the articular repair system can be porous coated thereby allowing in-growth. The surgeon can support the in-growth of bone by treating the subchondral bone with a rasp, typically to create a larger surface area and/or until bleeding from the subchondral bone occurs.

In another embodiment, the articular surface repair system can be attached to the underlying bone or bone marrow using bone cement. Bone cement is typically made from an acrylic polymeric material. Typically, the bone cement is comprised of two components: a dry powder component and a liquid component, which are subsequently mixed together. The dry component generally includes an acrylic polymer, such as polymethylmethacrylate (PMMA). The dry component can

also contain a polymerization initiator such as benzoylperoxide, which initiates the free-radical polymerization process that occurs when the bone cement is formed. The liquid component, on the other hand, generally contains a liquid monomer such as methyl methacrylate (MMA). The liquid component can also contain an accelerator such as an amine (e.g., N,N-dimethyl-p-toluidine). A stabilizer, such as hydroquinone, can also be added to the liquid component to prevent premature polymerization of the liquid monomer. When the liquid component is mixed with the dry component, the dry component begins to dissolve or swell in the liquid monomer. The amine accelerator reacts with the initiator to form free radicals that begin to link monomer units to form polymer chains. In the next two to four minutes, the polymerization process proceeds changing the viscosity of the mixture from a syrup-like consistency (low viscosity) into a dough-like consistency (high viscosity). Ultimately, further polymerization and curing occur, causing the cement to harden and affix a prosthesis to a bone.

In certain aspects, bone cement or another liquid attachment material such as injectable calciumhydroxyapatite can be injected into the marrow cavity through one or more openings in the prosthesis. These openings in the prosthesis can extend from the articular surface to the undersurface of the prosthesis. After injection, the openings can be closed with a polymer, silicon, metal, metal alloy or bioresorbable plug.

In another embodiment, one or more components of the articular surface repair (e.g., the surface of the system that is pointing towards the underlying bone or bone marrow) can be porous or porous coated. A variety of different porous metal coatings have been proposed for enhancing fixation of a metallic prosthesis by bone tissue in-growth. Thus, for example, U.S. Pat. No. 3,855,638 to Pilliar issued Dec. 24, 2974, discloses a surgical prosthetic device, which can be used as a bone prosthesis, comprising a composite structure consisting of a solid metallic material substrate and a porous coating of the same solid metallic material adhered to and extending over at least a portion of the surface of the substrate. The porous coating consists of a plurality of small discrete particles of metallic material bonded together at their points of contact with each other to define a plurality of connected interstitial pores in the coating. The size and spacing of the particles, which can be distributed in a plurality of monolayers, can be such that the average interstitial pore size is not more than about 200 microns. Additionally, the pore size distribution can be substantially uniform from the substrate-coating interface to the surface of the coating. In another embodiment, the articular surface repair system can contain one or more polymeric materials that can be loaded with and release therapeutic agents including drugs or other pharmacological treatments that can be used for drug delivery. The polymeric materials can, for example, be placed inside areas of porous coating. The polymeric materials can be used to release therapeutic drugs, e.g. bone or cartilage growth stimulating drugs. This embodiment can be combined with other embodiments, wherein portions of the articular surface repair system can be bioresorbable. For example, the first layer of an articular surface repair system or portions of its first layer can be bioresorbable. As the first layer gets increasingly resorbed, local release of a cartilage growth-stimulating drug can facilitate in-growth of cartilage cells and matrix formation.

In any of the methods or compositions described herein, the articular surface repair system can be pre-manufactured with a range of sizes, curvatures and thicknesses. Alternatively, the articular surface repair system can be custom-made for an individual patient.

IV. Manufacturing

A. Shaping

In certain instances shaping of the repair material will be required before or after formation (e.g., growth to desired thickness), for example where the thickness of the required cartilage material is not uniform (e.g., where different sections of the cartilage replacement or regenerating material require different thicknesses).

The replacement material can be shaped by any suitable technique including, but not limited to, mechanical abrasion, laser abrasion or ablation, radiofrequency treatment, cryoablation, variations in exposure time and concentration of nutrients, enzymes or growth factors and any other means suitable for influencing or changing cartilage thickness. See, e.g., WO 00/15153 to Mansmann published Mar. 23, 2000; If enzymatic digestion is used, certain sections of the cartilage replacement or regenerating material can be exposed to higher doses of the enzyme or can be exposed longer as a means of achieving different thicknesses and curvatures of the cartilage replacement or regenerating material in different sections of said material.

The material can be shaped manually and/or automatically, for example using a device into which a pre-selected thickness and/or curvature has been input and then programming the device using the input information to achieve the desired shape.

In addition to, or instead of, shaping the cartilage repair material, the site of implantation (e.g., bone surface, any cartilage material remaining, etc.) can also be shaped by any suitable technique in order to enhance integration of the repair material.

B. Sizing

The articular repair system can be formed or selected so that it will achieve a near anatomic fit or match with the surrounding or adjacent cartilage or subchondral bone or menisci and other tissue. The shape of the repair system can be based on the analysis of an electronic image (e.g. MRI, CT, digital tomosynthesis, optical coherence tomography or the like). If the articular repair system is intended to replace an area of diseased cartilage or lost cartilage, the near anatomic fit can be achieved using a method that provides a virtual reconstruction of the shape of healthy cartilage in an electronic image or, alternatively, the shape of the "failed implant" it replaces.

In one embodiment, a near normal cartilage surface at the position of the cartilage defect can be reconstructed by interpolating the healthy cartilage surface across the cartilage defect or area of diseased cartilage. This can, for example, be achieved by describing the healthy cartilage by means of a parametric surface (e.g. a B-spline surface), for which the control points are placed such that the parametric surface follows the contour of the healthy cartilage and bridges the cartilage defect or area of diseased cartilage. The continuity properties of the parametric surface will provide a smooth integration of the part that bridges the cartilage defect or area of diseased cartilage with the contour of the surrounding healthy cartilage. The part of the parametric surface over the area of the cartilage defect or area of diseased cartilage can be used to determine the shape or part of the shape of the articular repair system to match with the surrounding cartilage.

In another embodiment, a near normal cartilage surface at the position of the cartilage defect or area of diseased cartilage can be reconstructed using morphological image processing. In a first step, the cartilage can be extracted from the electronic image using manual, semi-automated and/or automated segmentation techniques (e.g., manual tracing, region growing, live wire, model-based segmentation), resulting in a

binary image. Defects in the cartilage appear as indentations that can be filled with a morphological closing operation performed in 2-D or 3-D with an appropriately selected structuring element. The closing operation is typically defined as a dilation followed by an erosion. A dilation operator sets the current pixel in the output image to 1 if at least one pixel of the structuring element lies inside a region in the source image. An erosion operator sets the current pixel in the output image to 1 if the whole structuring element lies inside a region in the source image. The filling of the cartilage defect or area of diseased cartilage creates a new surface over the area of the cartilage defect or area of diseased cartilage that can be used to determine the shape or part of the shape of the articular repair system to match with the surrounding cartilage or subchondral bone.

As described above, the articular repair system, including surgical tools and instruments, molds, in situ repair systems, etc. can be formed or selected from a library or database of systems of various sizes, curvatures and thicknesses so that it will achieve a near anatomic fit or match with the surrounding or adjacent cartilage and/or subchondral bone. These systems can be pre-made or made to order for an individual patient. In order to control the fit or match of the articular repair system with the surrounding or adjacent cartilage or subchondral bone or menisci and other tissues preoperatively, a software program can be used that projects the articular repair system over the anatomic position where it will be implanted. Suitable software is commercially available and/or readily modified or designed by a skilled programmer.

In yet another embodiment, the articular repair system including unicompartmental and total knee implants as well as hip devices can be projected over the implantation site using one or more 2-D or 3-D images. The cartilage and/or subchondral bone and other anatomic structures can be optionally extracted from a 2-D or 3-D electronic image such as an MRI or a CT using manual, semi-automated and/or automated segmentation techniques. A 2-D or 3-D representation of the cartilage and/or bone and other anatomic structures as well as the articular repair system can be generated, for example using a polygon or NURBS surface or other parametric surface representation. Ligaments, menisci and other articular structures can be displayed in 2-D and 3-D. For a description of various parametric surface representations see, for example Foley, J. D. et al., Computer Graphics: Principles and Practice in C; Addison-Wesley, 2nd edition, 1995).

The 2-D or 3-D representations of the cartilage and/or subchondral bone and other anatomic structures and the articular repair system can be merged into a common coordinate system. The articular repair system, including surgical tools and instruments, molds, in situ repair systems, etc. can then be placed at the desired implantation site. The representations of the cartilage, subchondral bone, ligaments, menisci and other anatomic structures and the articular repair system are rendered into a 2-D or 3-D image, for example application programming interfaces (APIs) OpenGL® (standard library of advanced 3-D graphics functions developed by SGI, Inc.; available as part of the drivers for PC-based video cards, for example from www.nvidia.com for NVIDIA video cards or www.3dlabs.com for 3Dlabs products, or as part of the system software for Unix workstations) or DirectX® (multimedia API for Microsoft Windows® based PC systems; available from www.microsoft.com). The 2-D or 3-D image can be rendered or displayed showing the cartilage, subchondral bone, ligaments, menisci or other anatomic objects, and the articular repair system from varying angles, e.g. by rotating or moving them interactively or non-interactively, in real-time or non-real-time.

In another embodiment, the implantation site may be visualized using one or more cross-sectional 2-D images, as described in U.S. Ser. No. 10/305,652, entitled "Methods and Compositions for Articular Repair," filed Nov. 27, 2002, which is hereby incorporated by reference in its entirety. Typically, a series of 2-D cross-sectional images will be used. The 2-D images can be generated with imaging tests such as CT, MRI, digital tomosynthesis, ultrasound, optical imaging, optical coherence tomography, other imaging modalities using methods and tools known to those of skill in the art. The articular repair system or implant can then be superimposed onto one or more of these 2-D images. The 2-D cross-sectional images may be reconstructed in other planes, e.g. from sagittal to coronal, etc. Isotropic data sets (e.g., data sets where the slice thickness is the same or nearly the same as the in-plane resolution) or near isotropic data sets can also be used. Multiple planes may be displayed simultaneously, for example using a split screen display. The operator may also scroll through the 2-D images in any desired orientation in real time or near real time; the operator can rotate the imaged tissue volume while doing this. The articular repair system or implant may be displayed in cross-section utilizing different display planes, e.g. sagittal, coronal or axial, typically matching those of the 2-D images demonstrating the cartilage, subchondral bone, ligaments, menisci or other tissue. Alternatively, a three-dimensional display may be used for the articular repair system. The 2-D electronic image and the 2-D or 3-D representation of the articular repair system or implant may be merged into a common coordinate system. The cartilage repair system or implant can then be placed at the desired implantation site. The series of 2-D cross-sections of the anatomic structures, the implantation site and the articular repair system or implant may be displayed interactively (e.g. the operator can scroll through a series of slices) or non-interactively (e.g. as an animation that moves through the series of slices), in real-time or non-real-time.

The software can be designed so that the articular repair system, including surgical tools and instruments, molds, in situ repair systems, etc. with the best fit relative to the cartilage and/or subchondral bone is automatically selected, for example using one or more of the techniques described above. Alternatively, the operator can select an articular repair system, including surgical tools and instruments, molds, in situ repair systems, etc. and project it or drag it onto the implantation site displayed on the cross-sectional 2-D or the 3-D images. The operator can then move and rotate the articular repair system relative to the implantation site and scroll through a cross-sectional 2-D or 3-D display of the articular repair system and of the anatomic structures. The operator can perform a visual and/or computer-assisted inspection of the fit between the articular repair system and the implantation site. This can be performed for different positions of the joint, e.g. extension, 45, 90 degrees of flexion, adduction, abduction, internal or external rotation. The procedure can be repeated until a satisfactory fit has been achieved. The procedure can be entirely manual by the operator; it can, however, also be computer-assisted. For example, the software can select a first trial implant that the operator can test (e.g., evaluate the fit). Software that highlights areas of poor alignment between the implant and the surrounding cartilage or subchondral bone or menisci or other tissues can also be designed and used. Based on this information, the software or the operator can select another implant and test its alignment.

In all of the above embodiments, the mechanical axis and relevant anatomical axes or planes can be displayed simultaneous with the joint and/or articular repair device in the 2-D or 3-D display. Simultaneous display of at least one or more

biomechanical axes or anatomical axes or planes can help improve the assessment of fit of the articular repair system. Biomechanical axis or relevant anatomical axes or planes can also be displayed for different positions of the joint.

C. Rapid Prototyping, Other Manufacturing Techniques

Rapid protyping is a technique for fabricating a three-dimensional object from a computer model of the object. A special printer is used to fabricate the prototype from a plurality of two-dimensional layers. Computer software sections the representations of the object into a plurality of distinct two-dimensional layers and then a three-dimensional printer fabricates a layer of material for each layer sectioned by the software. Together the various fabricated layers form the desired prototype. More information about rapid prototyping techniques is available in US Patent Publication No 2002/0079601A1 to Russell et al., published Jun. 27, 2002. An advantage to using rapid prototyping is that it enables the use of free form fabrication techniques that use toxic or potent compounds safely. These compounds can be safely incorporated in an excipient envelope, which reduces worker exposure

A powder piston and build bed are provided. Powder includes any material (metal, plastic, etc.) that can be made into a powder or bonded with a liquid. The power is rolled from a feeder source with a spreader onto a surface of a bed. The thickness of the layer is controlled by the computer. The print head then deposits a binder fluid onto the powder layer at a location where it is desired that the powder bind. Powder is again rolled into the build bed and the process is repeated, with the binding fluid deposition being controlled at each layer to correspond to the three-dimensional location of the device formation. For a further discussion of this process see, for example, US Patent Publication No 2003/017365A1 to Monkhouse et al. published Sep. 18, 2003.

The rapid prototyping can use the two dimensional images obtained, as described above in Section I, to determine each of the two-dimensional shapes for each of the layers of the prototyping machine. In this scenario, each two dimensional image slice would correspond to a two dimensional prototype slide. Alternatively, the three-dimensional shape of the defect can be determined, as described above, and then broken down into two dimensional slices for the rapid prototyping process. The advantage of using the three-dimensional model is that the two-dimensional slices used for the rapid prototyping machine can be along the same plane as the two-dimensional images taken or along a different plane altogether.

Rapid prototyping can be combined or used in conjunction with casting techniques. For example, a shell or container with inner dimensions corresponding to an articular repair system including surgical instruments, molds, alignment guides or surgical guides, can be made using rapid prototyping. Plastic or wax-like materials are typically used for this purpose. The inside of the container can subsequently be coated, for example with a ceramic, for subsequent casting. Using this process, personalized casts can be generated.

Rapid prototyping can be used for producing articular repair systems including surgical tools, molds, alignment guides, cut guides etc. Rapid prototyping can be performed at a manufacturing facility. Alternatively, it may be performed in the operating room after an intraoperative measurement has been performed.

Alternatively, milling techniques can be utilized for producing articular repair systems including surgical tools, molds, alignment guides, cut guides etc.

Alternatively, laser based techniques can be utilized for producing articular repair systems including surgical tools, molds, alignment guides, cut guides etc.

V. Implantation

Following one or more manipulations (e.g., shaping, growth, development, etc), the cartilage replacement, implant or regenerating material can then be implanted into the area of the defect. Implantation can be performed with the cartilage replacement or regenerating material still attached to the base material or removed from the base material. Any suitable methods and devices can be used for implantation, for example, devices as described in U.S. Pat. No. 6,375,658 to Hangody et al. issued Apr. 23, 2002; U.S. Pat. No. 6,358,253 to Torrie et al. issued Mar. 19, 2002; U.S. Pat. No. 6,328,765 to Hardwick et al. issued Dec. 11, 2001; and International Publication WO 01/19254 to Cummings et al. published Mar. 22, 2001.

In selected cartilage defects, the implantation site can be prepared with a single cut across the articular surface, for example. If desired, single and multi-component prostheses can be utilized.

V. Revision Implants, Systems and Methods

The various system and methods described herein may also be utilized to repair, revise or otherwise correct a previously-treated implant that has failed in some manner. Typically, joint replacement candidates, and the surgeries they experience, follow a "cascade" process, where less-invasive solutions and joint treatments are initially attempted and are eventually followed by more-invasive surgical procedures as the patient's joints and/or any implanted joint resurfacing and/or replacement components continue to degenerate. In the case of the knee joint, a patient can be diagnosed with a degenerative knee condition, and is preferably treated in a non-surgical manner until the joint has degenerated sufficiently to mandate surgical intervention. Minimally invasive repair techniques and/or partial knee replacement implants may be surgically implanted, but in most cases the degenerative process will continue, eventually requiring the implantation of a total knee replacement. As the degenerative cascade continues, total knee implants that require revision are typically assumed to involve significant bone loss, and often a lack of normal bony reference points or landmarks for properly aligning the implant. In these cases, surgeons often default to the use of the intramedullary canals of the femur and/or tibia as landmarks and/or anchoring points for positioning the various components of the revision prosthesis. Once such intramedullary stems are in place, further implant revision may be difficult or impossible, and may involve significantly more invasive procedures to anchor and/or position the prosthetic components. Alternatively, joint fusion may eventually be necessary.

Similar degenerative cascades are faced during virtually all joint replacement procedures, with each level of surgery typically involving more invasive surgical procedures, and often requiring removal of additional joint structure to accommodate the increasingly invasive revision prosthesis. As with virtually all types of joints, joint fusion is often the eventual "last resort."

One objective of this disclosure is to allow for accurate pre-operative assessment and modeling of the failed implant and associated anatomical structures, desirably to facilitate selection or design and manufacture of a revision implant and associated surgical tools that facilitate removal of the failed implant, preparation of the anatomical support structure, and implantation of the revision implant with preservation of a maximum of the existing anatomical support structure (i.e., underlying structures such as cortical and cancellous bone) while ensuring good support for the revision implant. Moreover, such objectives will desirably reduce or delay the need for anchoring support from intramedullary rods, which will

desirably be reserved for a "last step" in revision implant replacement for treating the degenerative cascade.

FIG. **1**A depicts various exemplary embodiments of a revision assessment and planning procedure. Initially, an image or images of the current failed implant and surrounding joint structure will be taken **10**. If available, additional historical image sets will desirably be obtained **20**, and these additional images may be cross-referenced against the "failed implant" set, as well as against each other, and evaluated and/or corrected **30**. In a related optional step, some or all of the images and/or processed/evaluated images will be further evaluated for artifact distortion, and corrected/evaluated as necessary **40**. Eventually, this process will desirably create a useful set of generated or "final" images for use in the preparation and planning phase of the implant revision process.

The evaluated and/or corrected final image set may then be used to select and/or create a revision implant, as well as to plan the surgical procedure and the surgical instruments used therein. In some embodiments, the revision implant will be chosen from a pre-formed library of implants **32**, or the revision implant may be created from a pre-existing electronic data file or may be custom designed as known in the art **34**. If an implant is selected from a pre-formed library, it can, optionally be adapted for the patient's anatomic or pathological conditions, for example using a CNC or other abrasion or additive process. Similarly, the final image set may be utilized to create custom surgical tools **36** for use in preparation of the anatomical support structures, either before **52** or after **54** removal of some or all of the failed implant components (or, in certain embodiments, some or all of the implant components may remain in situ). Once the site has been prepared, and any failed implant components removed (if desired), the revision implant is implanted.

i. Jigs and Surgical Alignment Tools

The various embodiments of this disclosure contemplate the design and manufacture of numerous surgical tools and jigs useful for preparing the anatomical structures for the revision implant. Desirably, the various surgical tools and jigs described herein will incorporate various patient-specific and/or implant specific features, including "failed" and revision implant features or dimensions, which facilitate their use during the preparation of anatomical structures and implantation of the revision implant components.

Aside from patient-specific anatomical features, the various embodiments contemplate the use of various features of the failed implant to assist in alignment and/or positioning of the various surgical tools and/or jigs. For example, it may be desirous to design and manufacture an alignment jig having one or more surfaces that fit over and/or abut against a portion of the failed implant (prior to removal of the failed implant from the patient's anatomy), optionally with one or more alignment guides for placement of alignment pins or other indicia (i.e., marker pins for cutting plane jigs, etc). After placement of such indicia, and removal of the jig and subsequently the failed implant, the preparation of the underlying anatomical support structure (for the revision implant) may proceed as known in the art. In this way, the use of intramedullary rods and other such alignment guides may be rendered superfluous and/or obviated, facilitating the preparation of appropriate bone structures without the sacrifice of unnecessary additional anatomical structures as is current practice in the art.

Table 3 provides a non-exhaustive list of various "failed implant" features that could be used as anatomical reference points from alignment and/or placement of surgical tools as described herein:

TABLE 3

Useful "Failed Implant" Features for Alignment

Misc Dimensions	A/P
	M/L
	S/I
	Combinations thereof
	Width
	Height
	Length
Surfaces	Exterior
	Interior
	Periphery
Mobile features	including dimensions of mobile bearing components
Cut Plane Features	Location, dimensions of chamfer and other cuts
Interlocking features	(i.e., modular components)
Misc. features	Pegs
	Stems
	Cavities (Created by Primary Stem)

In a similar manner, the various embodiments of surgical tools and/or jigs described herein could include various combinations of "failed implant" surfaces or features, patient-specific anatomical features and/or combinations thereof. For example, a jig could include surfaces that only interact and align with external surface(s) or other features of the "failed implant." Alternatively, the jig could include surfaces that only interact and align with external anatomical features of the patient (either those accessible with the "failed implant" in position within the anatomy, or those revealed after removal of some or all of the "failed implant" components. As another alternative, the jig could include surfaces that interact and align with both some external surface feature(s) of the "failed implant" as well as some accessible anatomical features. In various other embodiments, the jig may incorporate combinations of the above-listed interacting/alignment surfaces in concert with other surfaces that do not interact or align with either "failed implant" or accessible anatomical surfaces (i.e., surfaces that avoid contact or alignment, including "anatomical relief" surfaces disclosed in copending U.S. patent application Ser. No. 13/207,396). In addition, the jig could include surfaces that interact and align with the "failed implant" on one articular surface and an accessible anatomic surface or an anatomic surface revealed after removal of an implant component on the opposite articular surface.

The various jigs and other surgical tools disclosed herein could have numerous uses during the surgical preparation and implantation procedure, including (1) as guides for removal of cement or other biologic and non-biologic material(s), (2) as alignment and/or depth guides for creating/reaming an intramedullary canal, (3) as alignment or depth guides for creation of desirable anatomical features and/or cut planes, (4) as alignment guides for removal of osteophytes and/or other undesirable bone features, (5) as guides and/or molds for cement or other biologic/non-biologic placement, (6) as measuring or alignment guide for determining size and location of spacers, wedges, etc., (7) as guides to set a femoral, tibial, humeral, glenoid or other implant rotation (internal or external), orientation and/or anteversion or retroversion, flexion or extension (for the implant and/or a revision implant), (8) as jigs for ligament balancing, measuring or simulating flexion and extension gaps, (9) as jigs for placement of augments (spacers, wedges, etc., including non-patient specific and patient-specific augments, modular or non-modular components) or having openings or voids for accommodating augments, (10) as jigs for controlling component rotation or

flexion/extension or ante- or retroversion, NP cutting guides (optionally referencing medullary canal or peg holes from primary implant or from revision implant and/or anatomical features), (11) as jigs for augment cuts, and/or (12) as jigs for controlling the alignment of constraining features or mating components of revision implants. The various jig features can interact with anatomical and/or "failed implant" features (or combinations thereof) to align the implant along multiple planes, displacements and/or at one or more orientations to provide desired alignment data and/or provide one or more guides for preparation of the anatomical support structure for the revision implant. These features can be helpful in implanting devices that have constraining, mating or interlocking features.

Table 4 provides an non-exhaustive, exemplary list of proposed functions for surgical tools and jigs of the present invention:

TABLE 4

Surgical Tool and Jig Functions

jig for cement removal
femoral shaft
hip
humerus (patient specific on cortex, select burr, reamer, etc. on image)
burr/ream cement for removal
alignment guides for cutting/reaming/drilling tools
patient specific jig (anterior cortex) setting resection at defined height (e.g., below tibial plateau, based on information about residual bone/area of osteolysis, e.g. immediately inferior to or adjacent to areas of osteolysis)
jig for preparing femoral canal for revision implant/stem
facilitates/directs removal of material from canal
cement removal
cancellous bone removal
existing anchor removal
sets alignment prior to removal of primary stem
sets alignment relative to opposing joint surface or opposing implant surface
after primary stem has been pulled off
references off anterior, posterior or other cortex or resected bone (w/ or w/o bony defects, osteolysis)
references off resected femur (also tibia, humerus, other bones)
references off residual bone cement surfaces still integrated with bone
guides used with "failed implant" still in position
guides used after "failed implant" removed from joint, mating with bone surfaces (including, for example osteophytes or osteolytic areas, defects) exposed after removal of component or after removal of cement
Guide facilitates placement of marker(s) prior to removal of failed implant
defect correction
jig to assist in determination/correction of defects, osteolysis
accounts for use of wedges/spacers
jigs for setting anatomical features of implant
femoral or tibial rotation, flexion, extension
humeral or glenoid rotation, flexion, extension
jigs for placing markers having known or desirable alignment features
relative to anatomic axis
relative to mechanical axis of joint or limb
relative to intramedullary shaft
relative to endosteal bone
relative to cortical bone
relative to residual cement
relative to exposed bone surface after removal of implant and cement
relative to opposing surfaces of implant
relative to articulating surfaces of existing or "failed implant"
relative to constraining, interlocking or mating implant components
relative to bearing surfaces
relative to damaged polyethylene surfaces
relative to undamaged polyethylene surfaces

The following list provides various combinations of implants, jigs and support/alignment surfaces using tibia as an example contemplated by the present embodiments:

Tibia:
Implant removal tool
Cement removal tools
Burrs
Drills
Canal Preparation Tools (Reamers)
Provisional canal stem
Tibial boom (on top of stem)
Cutting guides (slots) on boom
Extramedullary arch (external guide rod holder)
Alignment rod (to arch) to determine mechanical axis
Tibial depth resection gauge (for lateral saw cut)
Tibial cutting head (pinned to tibia)
Stem provisional adapter (stabilizes the cutting saw)
Make cut (flat tibial plane now created)
Choose proper sizing plates by comparing them on resected tibial surface
Use alignment rod to verify vagus/varus alignment
Reinsert last intramedullary reamer or stem provisional assembly
Slide sizing plate over reamer/stem and seat (to align relative to stem)
Confirm use of proper wedges (if needed) and sizing plate
Pin the plate
Remove reamer/stem (use offset stem if necessary—or tibial augmentation)
Drill stem base for cemented stem
Use broach impactor
Remove broach impactor and sizing plate
Trial the tibial plate/stem

A. The Joint Replacement Procedure

i. Knee Joint

Performing a total knee arthroplasty (primary or revision procedure) is a complicated procedure. In replacing the knee with an artificial knee (or revising a failed or failing knee implant), it is important to get the anatomical and mechanical axes of the lower extremity aligned correctly to ensure optimal functioning of the implanted knee.

As shown in FIG. **11**A, the center of the hip **1902** (located at the head **1930** of the femur **1932**), the center of the knee **1904** (located at the notch where the intercondular tubercle **1934** of the tibia **1936** meet the femur) and ankle **1906** lie approximately in a straight line **1910** which defines the mechanical axis of the lower extremity. The anatomic axis **1920** aligns 5-7° offset θ from the mechanical axis in the valgus, or outward, direction.

The long axis of the tibia **1936** is collinear with the mechanical axis of the lower extremity **1910**. From a three-dimensional perspective, the lower extremity of the body ideally functions within a single plane known as the median anterior-posterior plane (MAP-plane) throughout the flexion-extension arc. In order to accomplish this, the femoral head **1930**, the mechanical axis of the femur, the patellar groove, the intercondylar notch, the patellar articular crest, the tibia and the ankle remain within the MAP-plane during the flexion-extension movement. During movement, the tibia rotates as the knee flexes and extends in the epicondylar axis which is perpendicular to the MAP-plane.

A variety of image slices can be taken at each individual joint, e.g., the knee joint **1950-1950**$_n$, and the hip joint **1952-1950**$_n$. These image slices can be used as described above in Section I along with an image of the full leg to ascertain the axis.

With disease and malfunction of the knee, alignment of the anatomic axis is altered. Performing a total knee arthroplasty is one solution for correcting a diseased knee. Implanting a total knee joint, such as the PFC Sigma RP Knee System by Johnson & Johnson, requires that a series of resections be made to the surfaces forming the knee joint in order to facilitate installation of the artificial knee. The resections should be made to enable the installed artificial knee to achieve flexion-extension movement within the MAP-plane and to optimize the patient's anatomical and mechanical axis of the lower extremity.

First, the tibia **1930** is resected to create a flat surface to accept the tibial component of the implant. In most cases, the tibial surface is resected perpendicular to the long axis of the tibia in the coronal plane, but is typically sloped 4-7° posteriorly in the sagittal plane to match the normal slope of the tibia. As will be appreciated by those of skill in the art, the sagittal slope can be 0° where the device to be implanted does not require a sloped tibial cut. The resection line **1958** is perpendicular to the mechanical axis **1910**, but the angle between the resection line and the surface plane of the plateau **1960** varies depending on the amount of damage to the knee.

FIGS. **11**B-D illustrate an anterior view of a resection of an anatomically normal tibial component, a tibial component in a varus knee, and a tibial component in a valgus knee, respectively. In each figure, the mechanical axis **1910** extends vertically through the bone and the resection line **1958** is perpendicular to the mechanical axis **1910** in the coronal plane, varying from the surface line formed by the joint depending on the amount of damage to the joint. FIG. **11**B illustrates a normal knee wherein the line corresponding to the surface of the joint **1960** is parallel to the resection line **1958**. FIG. **11**C illustrates a varus knee wherein the line corresponding to the surface of the joint **1960** is not parallel to the resection line **1958**. FIG. **11**D illustrates a valgus knee wherein the line corresponding to the surface of the joint **1960** is not parallel to the resection line **1958**.

Once the tibial surface has been prepared, the surgeon turns to preparing the femoral condyle.

The plateau of the femur **1970** is resected to provide flat surfaces that communicate with the interior of the femoral prosthesis. The cuts made to the femur are based on the overall height of the gap to be created between the tibia and the femur. Typically, a 20 mm gap is desirable to provide the implanted prosthesis adequate room to achieve full range of motion. The bone is resected at a 5-7° angle valgus to the mechanical axis of the femur. Resected surface **1972** forms a flat plane with an angular relationship to adjoining surfaces **1974**, **1976**. The angle θ', θ" between the surfaces **1972-1974**, and **1972-1976** varies according to the design of the implant.

ii. Hip Joint

As illustrated in FIG. **11**F, the external geometry of the proximal femur includes the head **1980**, the neck **1982**, the lesser trochanter **1984**, the greater trochanter **1986** and the proximal femoral diaphysis. The relative positions of the trochanters **1984**, **1986**, the femoral head center **1902** and the femoral shaft **1988** are correlated with the inclination of the neck-shaft angle. The mechanical axis **1910** and anatomic axis **1920** are also shown. Assessment of these relationships can change the reaming direction to achieve neutral alignment of the prosthesis with the femoral canal.

Using anteroposterior and lateral radiographs, measurements are made of the proximal and distal geometry to determine the size and optimal design of the implant.

Typically, after obtaining surgical access to the hip joint, the femoral neck **1982** is resected, e.g. along the line **1990**. Once the neck is resected, the medullary canal is reamed. Reaming can be accomplished, for example, with a conical or straight reamer, or a flexible reamer. The depth of reaming is dictated by the specific design of the implant. Once the canal has been reamed, the proximal reamer is prepared by serial rasping, with the rasp directed down into the canal.

B. Surgical Tools

Further, surgical assistance can be provided by using a device applied to the outer surface of the articular cartilage, the bone, including the subchondral bone, in order to match the alignment of the articular repair system and the recipient site or the joint. The device can be round, circular, oval, ellipsoid, curved or irregular in shape. The shape can be selected or adjusted to match or enclose an area of diseased cartilage or an area slightly larger than the area of diseased cartilage or substantially larger than the diseased cartilage. The area can encompass the entire articular surface or the weight bearing surface. Such devices are typically preferred when replacement of a majority or an entire articular surface is contemplated.

Mechanical devices can be used for surgical assistance (e.g., surgical tools), for example using gels, molds, plastics or metal. One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be utilized to either shape the device, e.g. using a CAD/CAM technique, to be adapted to a patient's articular anatomy or, alternatively, to select a typically premade device that has a good fit with a patient's articular anatomy. The device can have a surface and shape that will substantially match or conform to all or portions of the articular cartilage, subchondral bone and/or other bone surface and shape, e.g., similar to a "negative." The device can include, without limitation, one or more cut planes, apertures, slots and/or holes to accommodate surgical instruments such as drills, reamers, curettes, k-wires, screws and saws.

The device may have a single component or multiple components. The components may be attached to the unoperated and operated portions of the intra- or extra-articular anatomy. For example, one component may be attached to the femoral neck, while another component may be in contact with the greater or lesser trochanter. Typically, the different components can be used to assist with different parts of the surgical procedure. When multiple components are used, one or more components may also be attached to a different component rather than the articular cartilage, subchondral bone or other areas of osseous or non-osseous anatomy. For example, a tibial mold may be attached to a femoral mold and tibial cuts can be performed in reference to femoral cuts.

Components may also be designed to fit to the joint after an operative step has been performed. For example, in a knee, one component may be designed to fit all or portions of a distal femur before any cuts have been made, while another component may be designed to fit on a cut that has been made with the previously used mold or component. In a hip, one component may be used to perform an initial cut, for example through the femoral neck, while another subsequently used component may be designed to fit on the femoral neck after the cut, for example covering the area of the cut with a central opening for insertion of a reamer. Using this approach, subsequent surgical steps may also be performed with high accuracy, e.g. reaming of the marrow cavity.

In another embodiment, a guide may be attached to a mold to control the direction and orientation of surgical instruments. For example, after the femoral neck has been cut, a mold may be attached to the area of the cut, whereby it fits portions or all of the exposed bone surface. The mold may have an opening adapted for a reamer. Before the reamer is

introduced a femoral reamer guide may be inserted into the mold and advanced into the marrow cavity. The position and orientation of the reamer guide may be determined by the femoral mold. The reamer can then be advanced over the reamer guide and the marrow cavity can be reamed with improved accuracy. Similar approaches are feasible in the knee and other joints.

All mold components may be disposable. Alternatively, some molds components may be re-usable. Typically, mold components applied after a surgical step such as a cut as been performed can be reusable, since a reproducible anatomic interface will have been established.

Interconnecting or bridging components may be used. For example, such interconnecting or bridging components may couple the mold attached to the joint with a standard, preferably unmodified or only minimally modified cut block used during knee or hip surgery. Interconnecting or bridging components may be made of plastic or metal. When made of metal or other hard material, they can help protect the joint from plastic debris, for example when a reamer or saw would otherwise get into contact with the mold.

The accuracy of the attachment between the component or mold and the cartilage or subchondral bone or other osseous structures is typically better than 2 mm, more preferred better than 1 mm, more preferred better than 0.7 mm, more preferred better than 0.5 mm, or even more preferred better than 0.5 mm. The accuracy of the attachment between different components or between one or more molds and one or more surgical instruments is typically better than 2 mm, more preferred better than 1 mm, more preferred better than 0.7 mm, more preferred better than 0.5 mm, or even more preferred better than 0.5 mm.

The angular error of any attachments or between any components or between components, molds, instruments and/or the anatomic or biomechanical axes is preferably less than 2 degrees, more preferably less than 1.5 degrees, more preferably less than 1 degree, and even more preferably less than 0.5 degrees. The total angular error is preferably less than 2 degrees, more preferably less than 1.5 degrees, more preferably less than 1 degree, and even more preferably less than 0.5 degrees.

Typically, a position will be chosen that will result in an anatomically desirable cut plane, drill hole, or general instrument orientation for subsequent placement of an articular repair system or for facilitating placement of the articular repair system. Moreover, the device can be designed so that the depth of the drill, reamer or other surgical instrument can be controlled, e.g., the drill cannot go any deeper into the tissue than defined by the device, and the size of the hole in the block can be designed to essentially match the size of the implant. Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes. Alternatively, the openings in the device can be made larger than needed to accommodate these instruments. The device can also be configured to conform to the articular shape. The apertures, or openings, provided can be wide enough to allow for varying the position or angle of the surgical instrument, e.g., reamers, saws, drills, curettes and other surgical instruments. An instrument guide, typically comprised of a relatively hard material, can then be applied to the device. The device helps orient the instrument guide relative to the three-dimensional anatomy of the joint.

The mold may contact the entire articular surface. In various embodiments, the mold can be in contact with only a portion of the articular surface. Thus, the mold can be in contact, without limitation, with: 100% of the articular surface; 80% of the articular surface; 50% of the articular surface; 30% of the articular surface; 30% of the articular surface; 20% of the articular surface; or 10% or less of the articular surface. An advantage of a smaller surface contact area is a reduction in size of the mold thereby enabling cost efficient manufacturing and, more important, minimally invasive surgical techniques. The size of the mold and its surface contact areas have to be sufficient, however, to ensure accurate placement so that subsequent drilling and cutting can be performed with sufficient accuracy.

In various embodiments, the maximum diameter of the mold is less than 10 cm. In other embodiments, the maximum diameter of the mold may be less than: 8 cm; 5 cm; 4 cm; 3 cm; or even less than 2 cm.

The mold may be in contact with three or more surface points rather than an entire surface. These surface points may be on the articular surface or external to the articular surface. By using contact points rather than an entire surface or portions of the surface, the size of the mold may be reduced.

Reductions in the size of the mold can be used to enable minimally invasive surgery (MIS) in the hip, the knee, the shoulder and other joints. MIS technique with small molds will help to reduce intraoperative blood loss, preserve tissue including possibly bone, enable muscle sparing techniques and reduce postoperative pain and enable faster recovery. Thus, in one embodiment of this disclosure the mold is used in conjunction with a muscle sparing technique. In another embodiment, the mold may be used with a bone sparing technique. In another embodiment, the mold is shaped to enable MIS technique with an incision size of less than 15 cm, or, more preferred, less than 13 cm, or, more preferred, less than 10 cm, or, more preferred, less than 8 cm, or, more preferred, less than 6 cm.

The mold may be placed in contact with points or surfaces outside of the articular surface. For example, the mold can rest on bone in the intercondylar notch or the anterior or other aspects of the tibia or the acetabular rim or the lesser or greater trochanter. Optionally, the mold may only rest on points or surfaces that are external to the articular surface. Furthermore, the mold may rest on points or surfaces within the weight-bearing surface, or on points or surfaces external to the weight-bearing surface.

The mold may be designed to rest on bone or cartilage outside the area to be worked on, e.g. cut, drilled etc. In this manner, multiple surgical steps can be performed using the same mold. For example, in the knee, the mold may be stabilized against portions of the intercondylar notch, which can be selected external to areas to be removed for total knee arthroplasty or other procedures. In the hip, the mold may be attached external to the acetabular fossa, providing a reproducible reference that is maintained during a procedure, for example total hip arthroplasty. The mold may be affixed to the underlying bone, for example with pins or drills etc.

In additional embodiments, the mold may rest on the articular cartilage. The mold may rest on the subchondral bone or on structures external to the articular surface that are within the joint space or on structures external to the joint space. If the mold is designed to rest on the cartilage, an imaging test demonstrating the articular cartilage can be used in one embodiment. This can, for example, include ultrasound, spiral CT arthrography, MRI using, for example, cartilage displaying pulse sequences, or MRI arthrography. In another embodiment, an imaging test demonstrating the subchondral bone, e.g. CT or spiral CT, can be used and a standard cartilage thickness can be added to the scan. The standard cartilage thickness can be derived, for example, using an anatomic reference database, age, gender, and race matching,

age adjustments and any method known in the art or developed in the future for deriving estimates of cartilage thickness. The standard cartilage thickness may, in some embodiments, be uniform across one or more articular surfaces or it can change across the articular surface.

The mold may be adapted to rest substantially on subchondral bone. In this case, residual cartilage can create some offset and inaccurate result with resultant inaccuracy in surgical cuts, drilling and the like. In one embodiment, the residual cartilage is removed in a first step in areas where the mold is designed to contact the bone and the subchondral bone is exposed. In a second step, the mold is then placed on the subchondral bone.

In various alternative embodiments, the mold may include one or more surfaces that contact or interact with (i.e., match or substantially conform to) surfaces of a "failed implant".

With advanced osteoarthritis, significant articular deformity can result. The articular surface(s) can become flattened. There can be cyst formation or osteophyte formation. "Tram track" like structures can form on the articular surface. In one embodiment, osteophytes or other deformities may be removed by the computer software prior to generation of the mold. The software can automatically, semi-automatically or manually with input from the user simulate surgical removal of the osteophytes or other deformities, and predict the resulting shape of the joint and the associated surfaces. The mold can then be designed based on the predicted shape. Intraoperatively, these osteophytes or other deformities can then also optionally be removed prior to placing the mold and performing the procedure. Alternatively, the mold can be designed to avoid such deformities. For example, the mold may only be in contact with points on the articular surface or external to the articular surface that are not affected or involved by osteophytes. The mold can rest on the articular surface or external to the articular surface on three or more points or small surfaces with the body of the mold elevated or detached from the articular surface so that the accuracy of its position cannot be affected by osteophytes or other articular deformities. The mold can rest on one or more tibial spines or portions of the tibial spines. Alternatively, all or portions of the mold may be designed to rest on osteophytes or other excrescences or pathological changes.

The surgeon can, optionally, make fine adjustments between the alignment device and the instrument guide. In this manner, an optimal compromise can be found, for example, between biomechanical alignment and joint laxity or biomechanical alignment and joint function, e.g. in a knee joint flexion gap and extension gap. By oversizing the openings in the alignment guide, the surgeon can utilize the instruments and insert them in the instrument guide without damaging the alignment guide. Thus, in particular if the alignment guide is made of plastic, debris will not be introduced into the joint. The position and orientation between the alignment guide and the instrument guide can be also be optimized with the use of, for example, interposed spacers, wedges, screws and other mechanical or electrical methods known in the art.

A surgeon may desire to influence joint laxity as well as joint alignment. This can be optimized for different flexion and extension, abduction, or adduction, internal and external rotation angles. For this purpose, for example, spacers can be introduced that are attached or that are in contact with one or more molds. The surgeon can intraoperatively evaluate the laxity or tightness of a joint using spacers with different thickness or one or more spacers with the same thickness. For example, spacers can be applied in a knee joint in the presence of one or more molds and the flexion gap can be evaluated with the knee joint in flexion. The knee joint can then be extended and the extension gap can be evaluated. Ultimately, the surgeon will select an optimal combination of spacers for a given joint and mold. A surgical cut guide can be applied to the mold with the spacers optionally interposed between the mold and the cut guide. In this manner, the exact position of the surgical cuts can be influenced and can be adjusted to achieve an optimal result. Thus, the position of a mold can be optimized relative to the joint, bone or cartilage for soft-tissue tension, ligament balancing or for flexion, extension, rotation, abduction, adduction, anteversion, retroversion and other joint or bone positions and motion. The position of a cut block or other surgical instrument may be optimized relative to the mold for soft-tissue tension or for ligament balancing or for flexion, extension, rotation, abduction, adduction, anteversion, retroversion and other joint or bone positions and motion. Both the position of the mold and the position of other components including cut blocks and surgical instruments may be optimized for soft-tissue tension or for ligament balancing or for flexion, extension, rotation, abduction, adduction, anteversion, retroversion and other joint or bone positions and motion.

Someone skilled in the art will recognize other means for optimizing the position of the surgical cuts or other interventions. As stated above, expandable or ratchet-like devices may be utilized that can be inserted into the joint or that can be attached or that can touch the mold (see also FIG. **27**D). Such devices can extend from a cutting block or other devices attached to the mold, optimizing the position of drill holes or cuts for different joint positions or they can be integrated inside the mold. Integration in the cutting block or other devices attached to the mold is preferable, since the expandable or ratchet-like mechanisms can be sterilized and re-used during other surgeries, for example in other patients. Optionally, the expandable or ratchet-like devices may be disposable. The expandable or ratchet like devices may extend to the joint without engaging or contacting the mold; alternatively, these devices may engage or contact the mold. Hinge-like mechanisms are applicable. Similarly, jack-like mechanisms are useful. In principal, any mechanical or electrical device useful for fine-tuning the position of the cut guide relative to the molds may be used. These embodiments are helpful for soft-tissue tension optimization and ligament balancing in different joints for different static positions and during joint motion.

A surgeon may desire to influence joint laxity as well as joint alignment. This can be optimized for different flexion and extension, abduction, or adduction, internal and external rotation angles. For this purpose, for example, spacers or expandable or ratchet-like can be utilized that can be attached or that can be in contact with one or more molds. The surgeon can intraoperatively evaluate the laxity or tightness of a joint using spacers with different thickness or one or more spacers with the same thickness or using such expandable or ratchet like devices. For example, spacers or a ratchet like device can be applied in a knee joint in the presence of one or more molds and the flexion gap can be evaluated with the knee joint in flexion. The knee joint can then be extended and the extension gap can be evaluated. Ultimately, the surgeon will select an optimal combination of spacers or an optimal position for an expandable or ratchet-like device for a given joint and mold. A surgical cut guide can be applied to the mold with the spacers or the expandable or ratchet-like device optionally interposed between the mold and the cut guide or, in select embodiments, between the mold and the joint or the mold and an opposite articular surface. In this manner, the exact position of the surgical cuts can be influenced and can be adjusted to achieve an optimal result. Someone skilled in the art will

recognize other means for optimizing the position of the surgical cuts or drill holes. For example, expandable or ratchet-like devices can be utilized that can be inserted into the joint or that can be attached or that can touch the mold. Hinge-like mechanisms are applicable. Similarly, jack-like mechanisms are useful. In principal, any mechanical or electrical device useful for fine-tuning the position of the cut guide relative to the molds can be used.

The template and any related instrumentation such as spacers or ratchets can be combined with a tensiometer to provide a better intraoperative assessment of the joint. The tensiometer can be utilized to further optimize the anatomic alignment and tightness of the joint and to improve post-operative function and outcomes. Optionally, local contact pressures may be evaluated intraoperatively, for example using a sensor like the ones manufactured by Tekscan, South Boston, Mass. The contact pressures can be measured between the mold and the joint or between the mold and any attached devices such as a surgical cut block.

The template may be a mold that can be made of a plastic or polymer. The mold may be produced by rapid prototyping technology, in which successive layers of plastic are laid down, as know in the art. In other embodiments, the template or portions of the template can be made of metal. The mold can be milled or made using laser based manufacturing techniques.

The template may be casted using rapid prototyping and, for example, lost wax technique. It may also be milled. For example, a preformed mold with a generic shape can be used at the outset, which can then be milled to the patient specific dimensions. The milling may only occur on one surface of the mold, preferably the surface that faces the articular surface. Milling and rapid prototyping techniques may be combined.

Curable materials may be used which can be poured into forms that are, for example, generated using rapid prototyping. For example, liquid metal may be used. Cured materials may optionally be milled or the surface can be further refined using other techniques.

Metal inserts may be applied to plastic components. For example, a plastic mold may have at least one guide aperture to accept a reaming device or a saw. A metal insert may be used to provide a hard wall to accept the reamer or saw. Using this or similar designs can be useful to avoid the accumulation of plastic or other debris in the joint when the saw or other surgical instruments may get in contact with the mold. Other hard materials can be used to serve as inserts. These can also include, for example, hard plastics or ceramics.

In another embodiment, the mold does not have metallic inserts to accept a reaming device or saw. The metal inserts or guides may be part of an attached device that is typically in contact with the mold. A metallic drill guide or a metallic saw guide may thus, for example, have metallic or hard extenders that reach through the mold thereby, for example, also stabilizing any devices applied to the mold against the physical body of the mold.

The template may not only be used for assisting the surgical technique and guiding the placement and direction of surgical instruments. In addition, the templates can be utilized for guiding the placement of the implant or implant components. For example, in the hip joint, tilting of the acetabular component is a frequent problem with total hip arthroplasty. A template can be applied to the acetabular wall with an opening in the center large enough to accommodate the acetabular component that the surgeon intends to place. The template can have receptacles or notches that match the shape of small extensions that can be part of the implant or that can be applied to the implant. For example, the implant can have small members or extensions applied to the twelve o'clock and six o'clock positions. See, for example, FIG. **9**A-D, discussed below. By aligning these members with notches or receptacles in the mold, the surgeon can ensure that the implant is inserted without tilting or rotation. These notches or receptacles can also be helpful to hold the implant in place while bone cement is hardening in cemented designs.

One or more templates can be used during the surgery. For example, in the hip, a template can be initially applied to the proximal femur that closely approximates the 3D anatomy prior to the resection of the femoral head. The template can include an opening to accommodate a saw (see FIGS. **8-9**). The opening is positioned to achieve an optimally placed surgical cut for subsequent reaming and placement of the prosthesis. A second template can then be applied to the proximal femur after the surgical cut has been made. The second template can be useful for guiding the direction of a reamer prior to placement of the prosthesis. As can be seen in this, as well as in other examples, templates can be made for joints prior to any surgical intervention. However, it is also possible to make templates that are designed to fit to a bone, portions of a joint and/or surface of a "failed implant" after the surgeon has already performed selected surgical procedures, such as cutting, reaming, drilling, etc. The template can account for the shape of the bone or the joint resulting from these procedures.

In certain embodiments, the surgical assistance device comprises an array of adjustable, closely spaced pins (e.g., plurality of individually moveable mechanical elements). One or more electronic images or intraoperative measurements can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to create a surface and shape that will match all or portions of the articular and/or bone surface and shape by moving one or more of the elements, e.g. similar to an "image." The device can include slots and holes to accommodate surgical instruments such as drills, curettes, k-wires, screws and saws. The position of these slots and holes may be adjusted by moving one or more of the mechanical elements. Typically, a position will be chosen that will result in an anatomically desirable cut plane, reaming direction, or drill hole or instrument orientation for subsequent placement of an articular repair system or for facilitating the placement of an articular repair system.

Information about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of the, without limitation, cut planes, apertures, slots or holes on the template, in accordance with an embodiment of the invention. The biomechanical and/or anatomic axes may be derived using above-described imaging techniques including, without limitation, a standard radiograph, including a load bearing radiograph, for example an upright knee x-ray or a whole leg length film (e.g., hip to foot) These radiographs may be acquired in different projections, for example anteroposterior, posteroanterior, lateral, oblique etc. The biomechanical and anatomic axes may also be derived using other imaging modalities such as CT scan or MRI scan, a CT scout scan or MRI localized scans through portions or all of the extremity, either alone or in combination, as described in above embodiments. For example, when total or partial knee arthroplasty is contemplated, a spiral CT scan may be obtained through the knee joint. The spiral CT scan through the knee joint serves as the basis for generating the negative contour template(s)/mold(s) that will be affixed to portions or all of the knee joint. Additional CT or MRI scans may be

obtained through the hip and ankle joint. These may be used to define the centroids or centerpoints in each joint or other anatomic landmarks, for example, and then to derive the biomechanical and other axes.

In another embodiment, the mechanical axis may be established using non-image based approaches including traditional surgical instruments and measurement tools such as intramedullary rods, alignment guides and also surgical navigation. For example, in a knee joint, optical or radiofrequency markers can be attached to the extremity. The lower limb may then be rotated around the hip joint and the position of the markers can be recorded for different limb positions. The center of the rotation will determine the center of the femoral head. Similar reference points may be determined in the ankle joint etc. The position of the templates or, more typically, the position of surgical instruments relative to the templates may then be optimized for a given biomechanical load pattern, for example in varus or valgus alignment. Thus, by performing these measurements pre- or intraoperatively, the position of the surgical instruments may be optimized relative to the molds and the cuts can be placed to correct underlying axis errors such as varus or valgus malalignment or ante- or retroversion.

Upon imaging, a physical template of a joint, such as a knee joint, or hip joint, or ankle joint or shoulder joint is generated, in accordance with an embodiment of the invention. The template can be modified or analyzed using additional image groups, as previously described, and can be used to perform image guided surgical procedures such as partial or complete joint replacement, articular resurfacing, or ligament repair. The template may include reference points or opening or apertures for surgical instruments such as drills, saws, burrs and the like.

In order to derive the preferred orientation of drill holes, cut planes, saw planes and the like, openings or receptacles in said template or attachments will be adjusted to account for at least one axis (e.g., mechanical or anatomical). The axis can be anatomic or mechanical, for example, for a knee joint, a hip joint, an ankle joint, a shoulder joint or an elbow joint.

In one embodiment, only a single axis (e.g., mechanical or anatomical) is used for placing and optimizing such drill holes, saw planes, cut planes, and or other surgical interventions. This axis may be, for example, an anatomical or mechanical axis. In a preferred embodiment, a combination of axis and/or planes can be used for optimizing the placement of the drill holes, saw planes, cut planes or other surgical interventions. For example, two axes (e.g., one anatomical and one biomechanical) can be factored into the position, shape or orientation of the 3D guided template and related attachments or linkages. For example, two axes, (e.g., one anatomical and biomechanical) and one plane (e.g., the top plane defined by the tibial plateau), can be used. Alternatively, two or more planes can be used (e.g., a coronal and a sagittal plane), as defined by the image or by the patients anatomy.

Angle and distance measurements and surface topography measurements may be performed in these one or more, preferably two or more, preferably three or more multiple planes, as necessary. These angle measurements can, for example, yield information on varus or valgus deformity, flexion or extension deficit, hyper or hypo-flexion or hyper- or hypo-extension, abduction, adduction, internal or external rotation deficit, or hyper- or hypo-abduction, hyper- or hypo-adduction, hyper- or hypo-internal or external rotation.

Single or multi-axis line or plane measurements can then be utilized to determine preferred angles of correction, e.g., by adjusting surgical cut or saw planes or other surgical interventions. Typically, two axis corrections will be preferred over a single axis correction, a two plane correction will be preferred over a single plane correction and so forth.

In accordance with another embodiment, more than one drilling, cut, boring and/or reaming or other surgical intervention is performed for a particular treatment such as the placement of a joint resurfacing or replacing implant, or components thereof. These two or more surgical interventions (e.g., drilling, cutting, reaming, sawing) are made in relationship to a mechanical axis, and/or an anatomical axis and/or an implant axis. The 3D guidance template or attachments or linkages thereto include two or more openings, guides, apertures or reference planes to make at least two or more drillings, reamings, borings, sawings or cuts in relationship to a mechanical axis, an anatomical axis, an implant axis or other axis derived therefrom or related thereto.

While in simple embodiments it is possible that only a single cut or drilling will be made in relationship to a mechanical axis, an anatomical axis, an implant axis and/or an axis related thereto, in most meaningful implementations, two or more drillings, borings, reamings, cuttings and/or sawings will be performed or combinations thereof in relationship to a biomechanical, anatomical and/or implant axis.

For example, an initial cut may be placed in relationship to a mechanical axis of particular joint. A subsequent drilling, cut or other intervention can be performed in relation to an anatomical axis. Both can be designed to achieve a correction in a mechanical axis and/or anatomical axis. In another example, an initial cut can be performed in relationship to a mechanical axis, while a subsequent cut is performed in relationship to an implant axis or an implant plane. Any combination in surgical interventions and in relating them to any combination of biomechanical, anatomical, implant axis or planes related thereto is possible. In many embodiments, it is desirable that a single cut or drilling be made in relationship to a biomechanical or anatomical axis. Subsequent cuts or drillings or other surgical interventions can then be made in reference to said first intervention. These subsequent interventions can be performed directly off the same 3D guidance template or they can be performed by attaching surgical instruments or linkages or reference frames or secondary or other templates to the first template or the cut plane or hole and the like created with the first template.

FIG. **12** shows an example of a surgical tool **410** having one surface **400** matching the geometry of an articular surface of the joint. Also shown is an aperture **415** in the tool **410** capable of controlling drill depth and width of the hole and allowing implantation or insertion of implant **420** having a press-fit design.

In another embodiment, a frame can be applied to the bone or the cartilage in areas other than the diseased bone or cartilage. The frame can include holders and guides for surgical instruments. The frame can be attached to one or preferably more previously defined anatomic reference points. Alternatively, the position of the frame can be cross-registered relative to one, or more, anatomic landmarks, using an imaging test or intraoperative measurement, for example one or more fluoroscopic images acquired intraoperatively. One or more electronic images or intraoperative measurements including using mechanical devices can be obtained providing object coordinates that define the articular and/or bone surface and shape. These objects' coordinates can be entered or transferred into the device, for example manually or electronically, and the information can be used to move one or more of the holders or guides for surgical instruments. Typically, a position will be chosen that will result in a surgically or anatomically desirable cut plane or drill hole orientation for subsequent placement of an articular repair system. Information

about other joints or axis and alignment information of a joint or extremity can be included when selecting the position of these slots or holes.

Furthermore, re-useable tools (e.g., templates or molds) can be also be created and employed. Non-limiting examples of re-useable materials include putties and other deformable materials (e.g., an array of adjustable closely spaced pins that can be configured to match the topography of a joint surface).

In various embodiments, the template may include a reference element, such as a pin, that upon positioning of the template on the articular surface, establishes a reference plane relative to a mechanical axis or an anatomical axis or plane of a limb. For example, in a knee surgery the reference element may establish a reference plane from the center of the hip to the center of the ankle. In other embodiments, the reference element may establish an axis that subsequently be used a surgical tool to correct an axis deformity.

In these embodiments, the template can be created directly from the joint during surgery or, alternatively, created from an image of the joint, for example, using one or more computer programs to determine object coordinates defining the surface contour of the joint and transferring (e.g., dialing-in) these co-ordinates to the tool. Subsequently, the tool can be aligned accurately over the joint and/or existing implant component and, accordingly, the surgical instrument guide or the implant will be more accurately placed in or over the articular surface.

In both single-use and re-useable embodiments, the tool can be designed so that the instrument controls the depth and/or direction of the drill, i.e., the drill cannot go any deeper into the tissue than the instrument allows, and the size of the hole or aperture in the instrument can be designed to essentially match the size of the implant. The tool can be used for general prosthesis implantation, including, but not limited to, the articular repair implants described herein and for reaming the marrow in the case of a total arthroplasty.

These surgical tools (devices) can also be used to remove an area of diseased cartilage and underlying bone or an area slightly larger than the diseased cartilage and underlying bone. In addition, the device can be used on a "donor," e.g., a cadaveric specimen, to obtain implantable repair material. The device is typically positioned in the same general anatomic area in which the tissue was removed in the recipient. The shape of the device is then used to identify a donor site providing a seamless or near seamless match between the donor tissue sample and the recipient site. This can be achieved by identifying the position of the device in which the articular surface in the donor, e.g. a cadaveric specimen, has a seamless or near seamless contact with the inner surface when applied to the cartilage.

The device can be molded, rapid prototyped, machine and/or formed based on the size of the area of diseased cartilage and based on the curvature of the cartilage or the underlying subchondral bone or a combination of both or using adjacent structures inside or external to the joint space. The device can take into consideration surgical removal of, for example, the meniscus, in arriving at a joint surface configuration.

In one embodiment, the device can then be applied to the donor, (e.g., a cadaveric specimen) and the donor tissue can be obtained with use of a blade or saw or other tissue removing device. The device can then be applied to the recipient in the area of the joint and the diseased cartilage, where applicable, and underlying bone can be removed with use of a blade or saw or other tissue cutting device whereby the size and shape of the removed tissue containing the diseased cartilage will closely resemble the size and shape of the donor tissue. The donor tissue can then be attached to the recipient site. For example, said attachment can be achieved with use of screws or pins (e.g., metallic, non-metallic or bioresorable) or other fixation means including but not limited to a tissue adhesive. Attachment can be through the cartilage surface or alternatively, through the marrow space.

The implant site can be prepared with use of a robotic device. The robotic device can use information from an electronic image for preparing the recipient site.

Identification and preparation of the implant site and insertion of the implant can be supported by a surgical navigation system. In such a system, the position or orientation of a surgical instrument with respect to the patient's anatomy can be tracked in real-time in one or more 2D or 3D images. These 2D or 3D images can be calculated from images that were acquired preoperatively, such as MR or CT images. Non-image based surgical navigation systems that find axes or anatomical structures, for example with use of joint motion, can also be used. The position and orientation of the surgical instrument as well as the mold including alignment guides, surgical instrument guides, reaming guides, drill guides, saw guides, etc. can be determined from markers attached to these devices. These markers can be located by a detector using, for example, optical, acoustical or electromagnetic signals.

Identification and preparation of the implant site and insertion of the implant can also be supported with use of a C-arm system. The C-arm system can afford imaging of the joint in one or, preferably, multiple planes. The multiplanar imaging capability can aid in defining the shape of an articular surface. This information can be used to selected an implant with a good fit to the articular surface. Currently available C-arm systems also afford cross-sectional imaging capability, for example for identification and preparation of the implant site and insertion of the implant. C-arm imaging can be combined with administration of radiographic contrast.

In various embodiments, the surgical devices described herein can include one or more materials that harden to form a mold of the articular surface. In preferred embodiments, the materials used are biocompatible, such as, without limitation, acylonitrile butadiene styrene, polyphenylsulfone and polycarbonate. As used herein "biocompatible" shall mean any material that is not toxic to the body (e.g., produces a negative reaction under ISO 10993 standards, incorporated herein by reference). In various embodiments, these biocompatible materials may be compatible with rapid prototyping techniques.

In further embodiments, the mold material is capable of heat sterilization without deformation. An exemplary mold material is polyphenylsulfone, which does not deform up to a temperature of 207° C. Alternatively, the mold may be capable of sterilization using gases, e.g. ethyleneoxide. The mold may be capable of sterilization using radiation, e.g. γ-radiation. The mold may be capable of sterilization using hydrogen peroxide or other chemical means. The mold may be capable of sterilization using any one or more methods of sterilization known in the art or developed in the future.

A wide-variety of materials capable of hardening in situ include polymers that can be triggered to undergo a phase change, for example polymers that are liquid or semi-liquid and harden to solids or gels upon exposure to air, application of ultraviolet light, visible light, exposure to blood, water or other ionic changes. Any biocompatible material that is sufficiently flowable to permit it to be delivered to the joint and there undergo complete cure in situ under physiologically acceptable conditions can be used. The material can also be biodegradable.

The curable materials can be used in conjunction with a surgical tool as described herein. For example, the surgical

tool can be a template that includes one or more apertures therein adapted to receive injections and the curable materials can be injected through the apertures. Prior to solidifying in situ the materials will conform to the articular surface (subchondral bone and/or articular cartilage) facing the surgical tool and, accordingly, will form a negative impression of the surface upon hardening, thereby recreating a normal or near normal articular surface.

In addition, curable materials or surgical tools can also be used in conjunction with any of the imaging tests and analysis described herein, for example by molding these materials or surgical tools based on an image of a joint. For example, rapid prototyping may be used to perform automated construction of the template. The rapid prototyping may include the use of, without limitation, 3D printers, stereolithography machines or selective laser sintering systems. Rapid prototyping is a typically based on computer-aided manufacturing (CAM). Although rapid prototyping traditionally has been used to produce prototypes, they are now increasingly being employed to produce tools or even to manufacture production quality parts. In an exemplary rapid prototyping method, a machine reads in data from a CAD drawing, and lays down successive millimeter-thick layers of plastic or other engineering material, and in this way the template can be built from a long series of cross sections. These layers are glued together or fused (often using a laser) to create the cross section described in the CAD drawing.

FIG. **13** is a flow chart illustrating the steps involved in designing a mold for use in preparing a joint surface. Optionally, the first step can be to measure the size of the area of the diseased cartilage or cartilage loss **2100**, Once the size of the cartilage loss has been measured, the user can measure the thickness of the adjacent cartilage **2120**, prior to measuring the curvature of the articular surface and/or the subchondral bone **2130**. Alternatively, the user can skip the step of measuring the thickness of the adjacent cartilage **2102**. Once an understanding and determination of the shape of the subchondral bone is determined, either a mold can be selected from a library of molds **3132** or a patient specific mold can be generated **2134**. In either event, the implantation site is then prepared **2140** and implantation is performed **2142**. Any of these steps can be repeated by the optional repeat steps **2101**, **2121**, **2131**, **2133**, **2135**, **2141**.

A variety of techniques can be used to derive the shape of the template, as described above. For example, a few selected CT slices through the hip joint, along with a full spiral CT through the knee joint and a few selected slices through the ankle joint can be used to help define the axes if surgery is contemplated of the knee joint. Once the axes are defined, the shape of the subchondral bone can be derived, followed by applying standardized cartilage loss.

Methodologies for stabilizing the 3D guidance templates will now be described. The 3D guide template may be stabilized using multiple surgical tools such as, without limitation: K-wires; a drill bit anchored into the bone and left within the template to stabilize it against the bone; one or more convexities or cavities on the surface facing the cartilage; bone stabilization against intra/extra articular surfaces, optionally with extenders, for example, from an articular surface onto an extra-articular surface; and/or stabilization against newly placed cuts or other surgical interventions.

Specific anatomic landmarks (including landmarks from one or more surfaces of a "failed implant") may be selected in the design and make of the 3D guide template in order to further optimize the anatomic stabilization. For example, a 3D guidance template may be designed to cover portions or all off an osteophyte or bone spur in order to enhance anchoring of the 3D guide template against the underlying articular anatomy. The 3D guidance template may be designed to the shape of a trochlear or intercondylar notch and can encompass multiple anatomic areas such as a trochlea, a medial and a lateral femoral condyle at the same time. In the tibia, a 3D guide template may be designed to encompass a medial and lateral tibial plateau at the same time and it can optionally include the tibial spine for optimized stabilization and cross-referencing. In a hip, the fovea capitis may be utilized in order to stabilize a 3D guide template. Optionally, the surgeon may elect to resect the ligamentum capitis femoris in order to improve the stabilization. Also in the hip, an acetabular mold can be designed to extend into the region of the tri-radiate cartilage, the medial, lateral, superior, inferior, anterior and posterior acetabular wall or ring. By having these extensions and additional features for stabilization, a more reproducible position of the 3D template can be achieved with resulted improvement in accuracy of the surgical procedure. Typically, a template with more than one convexity or concavity or multiple convexities or concavities will provide better cross-referencing in the anatomic surface and higher accuracy and higher stabilization than compared to a mold that has only few surface features such as a singular convexity. Thus, in order to improve the implementation and intraoperative accuracy, careful surgical planning and preoperative planning is desired, that encompasses preferably more than one convexity, more preferred more than two convexities and even more preferred more than three convexities, or that encompasses more than one concavity, more preferred more than two concavities or even more preferred more than three concavities on an articular surface or adjoined surface, including bone and cartilage outside the weight-bearing surface.

In an even more preferred embodiment, more than one convexity and concavity, more preferred more than two convexities and concavities and even more preferred more then three convexities and concavities are included in the surface of the mold in order to optimize the interoperative cross-referencing and in order to stabilize the mold prior to any surgical intervention.

Turning now to particular 3D surgical template configurations and to templates for specific joint applications which are intended to teach the concept of the design as it would then apply to other joints in the body:

i. 3D Guidance Template Configurations/Positioning

The 3D guidance template may include a surface that duplicates the inner surface of an implant, an implant component, a "failed implant" surface, a "revision implant" surface and/or that conforms to an articular surface, at least partially, in accordance with an embodiment of the invention. More than one of the surfaces of the template may match or conform to one or more of the surfaces or portions of one or more of these surfaces of an implant, implant component, and/or articular surface.

FIG. **20** shows an example of a 3D guidance template **3000** in a hip joint, in accordance with one embodiment, wherein the template has extenders **3010** extending beyond the margin of the joint to provide for additional stability and to fix the template in place. The surface of the template facing the joint **3020** includes a portion that substantially conforms to a portion of the joint that is not affected by the arthritic process **3030**. By designing the template to have a surface portion that substantially conforms to at least a portion of the joint that is not affected by the arthritic process, greater reproducibility in placing the template can be achieved. In this design, the template spares the arthritic portions **3040** of the joint and does not include them in its joint facing surface. The template can optionally have metal sleeves **3050** to accommodate a

reamer or other surgical instruments, to protect a plastic. The metal sleeves or, optionally, the template can also include stops **3060** to limit the advancement of a surgical instrument once a predefined depth has been reached.

FIG. **21** shows another embodiment of a 3D guidance template **3100** for an acetabulum, in accordance with an embodiment of the invention. The articular surface is roughened **3110** in some sections by the arthritic process. At least a portion of the template **3120** is made to be a portion that substantially conforms to of the articular surface altered by the arthritic process **3110**. By matching the template to the joint in areas where it is altered by the arthritic process improved intraoperative localization and improved fixation can be achieved. In other section, the template can be matched to portions of the joint that are not altered by the arthritic process **3130**.

FIG. **22** shows another embodiment of a 3D guidance template **3200** designed to guide a posterior cut **3210** using a posterior reference plane **3220**. The joint facing surface of the template **3230** includes a portion that substantially conforms to one or more portions of the joint that are not altered by the arthritic process. The arthritic process includes an osteophyte **3240**. The template includes a recess **3250** that helps avoid the osteophyte **3240**. The template is at least in part substantially matched to portions of the joint that are not involved by the arthritic process.

FIG. **23** shows another embodiment of a 3D guidance template **3300** designed to guide an anterior cut **3310** using an anterior reference plane **3320**. The joint facing surface of the template **3230** includes a portion that substantially conforms to one or more portions of the joint that are altered by the arthritic process. The arthritic process includes an osteophyte **3240**. The joint facing surface of the template **3230** includes a portion that substantially conforms to the arthritic process, at least in part, including the osteophyte **3240**. The template is at least in part substantially matched to portions of the joint that are involved by the arthritic process.

FIG. **24** shows another embodiment of a 3D guidance template **3400** for guiding a tibial cut (not shown), wherein the tibia **3410** includes an arthritic portion **3420**, in this example a subchondral cyst **3430**. The template is designed to avoid the arthritic process by spanning across **3440** the defect or cyst.

FIG. **25** shows another embodiment of a 3D guidance template **3500** for guiding a tibial cut (not shown), wherein the tibia **3510** includes an arthritic portion **3520**, in this example a subchondral cyst **3530**. The template is designed to include the arthritic process **3520** by extending into **3540** the defect or cyst **3530**. The surface of the template facing the joint **3550** includes a portion that substantially conforms to one or more portions of normal joint **3560** and portions of the joint that are altered by the arthritic process **3530**. The interface between normal and arthritic tissue is included in the shape of the template **3520**.

FIGS. **26**A-D show a knee joint with a femoral condyle **3600** including a normal **3610** and arthritic **3620** region, in accordance with various embodiments of the invention. The interface **3630** between normal **3610** and arthritic **3620** tissue is shown. The template is designed to guide a posterior cut **3640** using a guide plane **3650** or guide aperture **3660**.

In one embodiment shown in FIG. **26**A the surface of the template facing the joint **3670** includes a portion that substantially conforms to at least portions of the surface of the joint that is healthy or substantially unaffected by the arthritic process. A recessed area **3670** can be present to avoid contact with the diseased joint region. This design can be favorable when an imaging test is used that does not provide sufficient detail about the diseased region of the joint to accurately generate a template, or where information about the anatomical margins of the underlying anatomical support structure are of insufficient "confidence" as desired by the user/operator.

In a similar embodiment shown in FIG. **26**B the surface of the template facing the joint **3670** includes a portion that substantially conforms to at least portions of the surface of the joint that is healthy or substantially unaffected by the arthritic process. The diseased area **3620** is covered by the template, but the template is not substantially in contact with it.

In another embodiment shown in FIG. **26**C the surface of the template facing the joint **3670** includes a portion that substantially conforms to at least portions of the surface of the joint that are arthritic. The diseased area **3620** is covered by the template, and the template is in close contact with it. This design can be advantageous to obtain greater accuracy in positioning the template if the arthritic area is well defined on the imaging test, e.g. with high resolution spiral CT or near isotropic MRI acquisitions or MRI with image fusion. This design can also provide enhanced stability during surgical interventions by more firmly fixing the template against the irregular underlying surface.

In another embodiment shown in FIG. **26**D the surface of the template facing the joint **3670** includes a portion that substantially conforms to at least portions of the surface of the joint that are arthritic. The diseased area **3620** is covered by the template, and the template is in close contact with it. Moreover, healthy or substantially normal regions **3610** are covered by the template and the template is in close contact with them. The template is also closely mirroring the shape of the interface between substantially normal or near normal and diseased joint tissue **3630**. This design can be advantageous to obtain even greater accuracy in positioning the template due to the change in surface profile or contour at the interface and resultant improved placement of the template on the joint surface. This design can also provide enhanced stability during surgical interventions by more firmly fixing and anchoring the template against the underlying surface and the interface **3630**.

The template may include guide apertures or reference points for two or more planes, or at least one of a cut plane and one of a drill hole or reaming opening for a peg or implant stem, in accordance with an embodiment of the invention.

The distance between two opposing, articulating implant components may be optimized intraoperatively for different pose angles of the joint or joint positions, such as different degrees of section, extension, abduction, adduction, internal and external rotation. For example, spacers, typically at least partially conforming to the template, may be placed between the template of the opposite surface, where the opposite surface can be the native, uncut joint, the cut joint, the surgically prepared joint, the trial implant, the failed implant, the revision implant and/or any other implant component for that articular surface. Alternatively, spacers may be placed between the template and the articular surface for which it will enable subsequent surgical interventions. For example, by placing spacers between a tibial template and the tibia, the tibial cut height can be optimized. The thicker the spacer, or the more spacers interposed between the tibial template and the tibial plateau, the less deep the cut will be, i.e. the less bone will be removed from the top of the tibia.

The spacers may be non-conforming to the template, e.g. they may be of a flat nature. The spacers may be convex or concave or include multiple convexities or concavities. The spacers may be partially conforming to the template. For example, in one embodiment, the surface of the spacer

optionally facing the articular surface can be molded and individualized to the articular surface, thereby forming a template/mold, while the opposite surface of the spacer can be flat or curved or have any other non-patient specific design. The opposite surface may allow for placement of blocks or other surgical instruments or for linkages to other surgical instruments and measurement devices.

In another embodiment, the template may include multiple slots spaced at equal distance or at variable distances wherein these slots allow to perform cuts at multiple cut heights or cut depths that can be decided on intraoperatively. In another embodiment, the template may include a ratchet-like mechanism wherein the ratchet can be placed between the articular surface and the template or between the template and the opposite surface wherein the opposite surface may include the native, uncut opposite surface, the cut opposite surface, an opposite surface template, a trial implant or the implant component designed for the opposite surface. By using a ratchet-like device, soft tissue tension can be optimized, for example, for different pose angles of the joint or joint positions such as flexion, extension, abduction, adduction, internal rotation and external rotation at one or more degrees for each direction.

Optimizing soft tissue tension will improve joint function that advantageously enhances postoperative performance. Soft tissue tension may, for example, be optimized with regard to ligament tension or muscle tension but also capsular tension. In the knee joint, soft tissue tension optimization includes typically ligament balancing, e.g. the cruciate ligaments and/or the collateral ligaments, for different degrees of knee flexion and knee extension.

In a preferred embodiment, a 3D guidance template may attach to two or more points on the joint and/or implant component. In an even more preferred embodiment, a template may attach to three or more points, even more preferred four or more points, even more preferred five or more points, even more preferred six or more points, even more preferred seven or more points, even more preferred ten or more points, even more preferred portions for the entire surface to be replaced.

In another embodiment, the template may include one or more linkages for surgical instruments. The linkages may also be utilized for attaching other measurement devices such as alignment guides, intramedullary guides, laser pointing devices, laser measurement devices, optical measurement devices, radio frequency measurement devices, surgical navigation and the like. Someone skilled in the art will recognize many surgical instruments and measurement in alignment devices may be attached to the template. Alternatively, these surgical instruments or alignment devices may be included within the template.

In another embodiment, a link or a linkage may be attached or may be incorporated or may be part of a template that rests on a first articular or implant surface. Said link or linkage may further extend to a second articular or implant surface which is typically an opposing articular surface. Said link or linkage can thus help cross-reference the first surface with the second surface, ultimately assisting the performance of surgical interventions on the second surface using the cross reference to the first surface. The second surface may optionally be cut with a second template. Alternatively, the second surface may be cut using a standard surgical instrument, non-individualized, that is cross referenced via the link to the surgical mold placed on the first surface. The link or linkage may include adjustment means, such as ratchets, telescoping devices and the like to optimize the spatial relationship between the first surface and the second, opposing articular surface. This optimization may be performed for different degrees of joint flexion, extension, abduction, adduction and rotation.

In another embodiment, the linkage may be made to the cut articular surface or, more general, an articular surface that has been altered using a template and related surgical intervention. Thus, cross reference can be made from the first articular surface from a mold attached to said first articular surface, the mold attached to a surgically altered, for example, cut articular surface, the surgical instrument attached to said articular surface altered using the mold, e.g. cut or drilled, and the like. Someone skilled in the art will easily recognize multiple different variations of this approach. Irrespective of the various variations, in a first step the articular surface is surgically altered, for example, via cutting, drilling or reaming using a mold while in the second step cross reference is established with a second articular surface.

By establishing cross reference between said first and said second articular surface either via the template and/or prior to or after a surgical intervention, the surgical intervention performed on the second articular surface can be performed using greater accuracy and improved usability in relation to said articulating, opposing first articular surface.

FIGS. **27**A-D show multiple templates with linkages on the same articular surface (A-C) and to an opposing articular surface (D), in accordance with various embodiments of the invention. The mechanical axis is denoted as **3700**. A horizontal femoral cut **3701**, an anterior femoral cut **3702**, a posterior femoral cut **3703**, an anterior chamfer cut **3704** and a posterior chamfer cut **3705** are planned in this example. A first template **3705** is applied in order to determine the horizontal cut plane and to perform the cut. The cut is perpendicular to the mechanical axis **3700**. The first template **3705** has linkages or extenders **3710** for connecting a second template **3715** for the anterior cut **3702** and for connecting a third template **3720** for the posterior cut **3703**. The linkages **3710** connecting the first template **3705** with the second **3715** and third template **3720** help in achieving a reproducible position of the templates relative to each other. At least one of the templates, preferably the first template **3705**, will have a surface **3706** that includes a portion that substantially conforms to at least a portion of the articular surface **3708**. In this example, all three templates have surfaces facing the joint that includes one or more portions that substantially conform to one or more portions of the joint, although one template having a surface conforming to the joint suffices in many applications as described herein.

A fourth template **3725** may optionally be used in order to perform an anterior chamfer cut **3704**. The fourth template may have a guide aperture or reference plane **3730** that can determine the anterior chamfer cut **3704**. The fourth template can, but must not have at least one surface **3735** matching one or more cut articular surfaces **3740**. The fourth template may have one or more outriggers or extenders **3745** stabilizing the template against the cut or uncut articular surface.

A fifth template **3750** may optionally be used to perform a anterior chamfer cut **3705**. The fifth template may have a guide aperture or reference plane **3755** that can determine the posterior chamfer cut **3705**. The fifth template may have at least one surface **3735** matching one or more cut articular surfaces **3740**. Oblique planes **3760** may help to further stabilize the template during the procedure. The fifth template may have one or more outriggers or extenders **3745** stabilizing the template against the cut or uncut articular surface.

In another embodiment, an opposite articular side **3765** may be cut in reference to a first articular side **3766**. Any order or sequence of cutting is possible: femur first then tibia, tibia first then femur, patella first, and so forth. A template **3770**

may be shaped to the uncut or, in this example, cut first articular side. The template may have stabilizers against the first articular surface, for example with extenders **3772** into a previously created peg hole **3773** for an implant. The template may have a linkage or an extender **3775** to a second articular surface **3765**. Surgical instruments may be attached to the linkage or extender **3775**. In this example, a tibial cut guide **3778** with multiple apertures or reference planes **3779** for a horizontal tibial cut is attached. The tibial cut guide may but may not have a surface matching the tibial surface.

By referencing a first, e.g. femoral, to a second, e.g. tibial cut greater accuracy can be achieved in the alignment of these cuts, which will result in improved implant component alignment and less wear. Ratchet like devices **3785** or hinge like devices or spacers may be inserted into the space between the first and the second articular surface and soft-tissue tension and ligament balancing can be evaluated for different distances achieved between the first **3766** and second **3765** articular surface, with one or more of them being cut or uncut. In this manner, soft-tissue tension and ligament balancing can be tested during different pose angles, e.g. degrees of flexion or extension. Optionally, tensiometers can be used. Once an ideal soft-tissue tension and/or ligament balancing has been achieved, the tibial cut may be performed through one of the guide apertures **3779** in reference to the femoral cut.

FIG. **28** is an example demonstrating a deviation in the AP plane of the femoral **3801** and tibial **3803** axes in a patient. Axis deviations can be determined in any desired plane including the AP plane, not only the ML plane. The axis deviation can be measured. The desired correction can be determined and the position, orientation and shape of a 3D guidance template can be adjusted in order to achieve the necessary correction. The correction may, for example, be designed to achieve a result wherein the femoral **3801** and tibial **3803** axes will coincide with the mechanical axis **3805**.

This disclosure optionally provides for trial implants and trial devices that help test intraoperatively the result of the surgical intervention achieved using the 3D guidance mold. Trial implants or devices can be particularly useful for subsequent adjustments and fine-tuning of the surgical intervention, for example, optimizing soft tissue tension in different articular pose angles.

In another embodiment, the templates may also allow for intraoperative adjustments. For example, the template may include an opening for a pin. The pin can be placed in the bone and the template can be rotated around the pin thereby optimizing, for example, medial and lateral ligament tension in a knee joint or thereby optimizing the cut orientation and resultant rotation and alignment of an implant relative to the anatomic or mechanical axis.

In another embodiment, standard tools including alignment guides may be attached to the mold, via linkages, for example, and the attachment can allow for additional adjustments in mold and subsequently implant alignment and rotation.

The above-described embodiments can be particularly useful for optimization of soft tissue tension including ligament balancing, for example, in a knee joint. Optimization of soft tissue tension can advantageously improve post-operative function and range of motion.

Linkages may also be utilized to stabilize and fix additional molds or surgical instruments on the articular surface.

Moreover, linkages can allow separation of one large mold into multiple smaller molds. The use of multiple smaller, linked molds advantageously enable smaller surgical axis with the potential to enhance muscle sparing and to reduce the size of the skin cut.

In another embodiment, all or portions of the template may be made of metal, metal-alloys, teflon, ceramics. In a more preferred embodiment, metal, metal-alloys, teflon, ceramics and other hard materials, typically materials that offer a hardness of, without limitation, greater than shore 60D, is placed in areas where the surgical instruments will be in contact with the template.

iii. Impingement Syndromes, Removal of Exophytic Bone Growth Including Osteophytes

3D guidance templates may also be utilized to treat impingement syndromes, for example, by template guided removal of osteophytes or exophytic bone growth. In one embodiment, an imaging test such as a CT scan or an MRI scan is obtained through the area of concern. If a joint is imaged, the images can demonstrate an osteophyte or, more generally, exophytic bone growth in intra and extra-articular locations. The scan data may then be utilized to design a template that matches the surface adjacent to the exophytic bone growth or osteophyte, the surface overlying the exophytic bone growth or osteophyte or both or portions of one or both. The template may have openings or apertures or linkages that allow placement of surgical tools for removal of the exophytic bone growth or the osteophyte, such as reamers, drills, rotating blades and the like. Someone skilled in the art will recognize many different surgical instruments that can be utilized in this manner.

Two representative examples where a 3D guidance template can be applied to treat local impingement syndromes are the pincer and Cam impingement syndromes in the hip joint. Pincer and Cam impingement represent femoro-acetabular impingement syndromes caused by an abutment between the proximal femur and the acetabular rim during the end range of motion. Untreated femoral-acetabular impingement can cause osteoarthritis of the hip.

In Cam impingement, a non-spherical portion of the femoral head, typically located near the head-neck junction, is jammed into the acetabulum during hip joint motion. The Cam impingement can lead to considerable shear forces and subsequently chondral erosion.

In one embodiment, an imaging test, such as a CT scan or MRI scan may be performed pre-operatively. The imaging test may be used to identify the non-spherical portion of the femoral head at the head-neck junction that is responsible for the impingement. A 3D guidance template may be designed that can be applied intraoperatively to this region. The template is designed to fulfill three principle functions:

1. Intraoperative highly accurate identification of the non-spherical portion of the femoral head by placement of the individualized portion of the 3D template onto the area or immediately adjacent to the area.

2. Guidance of surgical instrumentation to remove the non-spherical portion and to re-establish a spherical or essentially spherical shape.

3. Control of the depth of the bone removal and the shape of the bone removal. For this purpose, a stop may be incorporated into the design of the 3D guidance template. Of note, the stop may be asymmetrical and can even be designed to have a shape that is substantially a negative of the desired articular contour.

FIG. **31** shows an example of treatment of CAM impingement using a 3D guidance template **4100**. The impinging area **4105** may be removed with a saw (not shown) inserted into the guide aperture **4110**. The guide aperture may be designed and placed so that only the impinging portion of the joint is removed.

In Pincer impingement, linear bony contact occurs between the normal femoral head-neck junction and enlarged

or hypertrophied portion of the acetabulum. Pre-operatively an imaging test may be performed in order to identify the abnormal, over covered or enlarged area of the acetabulum. The amount of bone removal may be determined on the imaging study, e.g. a CT scan or MRI scan. A 3D guidance template may then be designed that will achieve the identical three functions described above in Cam impingement.

FIG. **32** shows an example of treatment of Pincer impingement using a 3D guidance template **4200**. The impinging area **4205** may be removed with a saw (not shown) inserted into the guide aperture **4210**. The guide aperture may be designed and placed so that only the impinging portion of the joint is removed.

Accurate and reproducible identification of the abnormal bony surface causing the impingement is critical in any form of musculoskeletal impingement syndrome. 3D guidance template systems are ideally suited to achieve this purpose and to guide the surgical instrumentation for removal of the source of impingement. Moreover, since the localization of the impinging area is performed pre-operatively during the imaging test, and intra-operatively using the 3D guidance template, this approach allows for minimally invasive, tissue, specifically muscle sparing approaches.

iv. Surgical Navigation and 3D Guidance Templates

3D guidance template technology as described herein may be combined with surgical navigation techniques. Surgical navigation techniques may be image guided or non-image guided for this purpose. Passive or active surgical navigation systems may be employed. Surgical navigation systems that use optical or radiofrequency transmission or registration may be used. A representative example is the Vector Vision navigation system manufactured by Brain Lab, Germany. This is a passive infrared navigation system. Once the patient is positioned appropriately in the operating room, retro-reflective markers can be applied to the extremity near the area of intended surgery. With image guided navigation, an imaging study such as a CT scan or MRI scan, can be transferred into the workstation of the navigation system. For registration purposes, the surgeon can, for example, utilize a pointer navigation tool to touch four or more reference points that are simultaneously co-identified and cross registered on the CT or MRI scan on the workstation. In the knee joint, reference points may include the trochlear groove, the most lateral point of the lateral condyle, the most medial femoral condyle, the tip of the tibial spines and so forth. Using image guided navigation, anatomical and mechanical axis of the joint can be determined reliably.

Alternatively, non-image guided navigation may be utilized. In this case, retro-reflective markers or small radio frequency transmitters are positioned on the extremity. Movement of the extremity and of the joints is utilized, for example, to identify the center of rotation. If surgery of the knee joint is contemplated, the knee joint may be rotated around the femur. The marker or radiofrequency transmitter motion may be utilized to identify the center of the rotation, which will coincide with the center of the femoral head. In this manner, the mechanical axis may be determined non-invasively.

The information resulting in imaging guided navigation, pertaining to either anatomical or mechanical axis can be may be utilized to optimize the position of any molds, blocks, linkages or surgical instruments attached to or guided through the 3D guidance molds.

In one embodiment, the joint or more specifically the articular surface, may be scanned intra-operatively, for example, using ultrasound or optical imaging methods. The optical imaging methods may include stereographic or stereographic like imaging approaches, for example, multiple light path stereographic imaging of the joint and the articular surface or even single light path 3D optical imaging. Other scan technologies that are applicable are, for example, C-arm mounted fluoroscopic imaging systems that can optionally also be utilized to generate cross-sectional images such as a CT scan. Intraoperative CT scanners are also applicable. Utilizing the intraoperative scan, a point cloud of the joint or the articular surface or a 3D reconstruction or a 3D visualization and other 3D representations may be generated that can be utilized to generate an individualized template wherein at least a portion of said template includes a surface that includes a portion that substantially conforms to the joint (e.g., including non-articular surface portions) or the articular surface. A rapid prototyping or a milling or other manufacturing machine can be available in or near the operating room and the 3D guidance template may be generated intraoperatively.

The intraoperative scan in conjunction with the rapid production of an individualized 3D guidance template matching the joint or the articular surface, in whole or at least in part, has the advantage to generate rapidly a tool for rapid intraoperative localization of anatomical landmarks, including articular landmarks. A 3D guidance template may then optionally be cross-registered, for example, using optical markers or radiofrequency transmitters attached to the template with the surgical navigation system. By cross-referencing the 3D guidance template with the surgical navigation system, surgical instruments can now be reproducibly positioned in relationship to the 3D guidance template to perform subsequent procedures in alignment with or in a defined relationship to at least one or more anatomical axis and/or at least one or more mechanical axis or planes.

v. Stereoscopy, Stereoscopic Imaging:

In addition to cross-sectional or volumetric imaging technologies including CT, spiral CT, and MRI, stereoscopic imaging modalities may be utilized. Stereoscopic imaging is any technique capable of recording three-dimensional information from two two-dimensional, projectional imaging. Traditional stereoscopic imaging includes creating a 3D visualization or representation starting from a pair of 2D images. The projection path of the 2D images is offset. The offset is, for example, designed to create an impression of object depth for the eyes of the viewer. The offset or minor deviation between the two images is similar to the prospectors that both eyes naturally receive inbinocular vision. Using two or more images with an offset or minor deviation in perspective, it is possible to generate a point cloud or 3D surface or 3D visualization of a joint or an articular surface, which can then be input into a manufacturing system such as a rapid prototyping or milling machine. Dual or more light path, as well as single light path, systems can be employed

vi. Knee Joint

When a revision procedure for a total knee arthroplasty (or repair of a less-than-total knee implant device) is contemplated, the patient can undergo an imaging test, as discussed in more detail above, that will demonstrate the articular anatomy of the knee joint as well as the condition and image of the existing "failed implant," e.g. width of the femoral condyles, the tibial plateau, artifact images, etc. Additionally, other joints can be included in the imaging test thereby yielding information on femoral and tibial axes, deformities such as varus and valgus and other articular alignment. The imaging test can be an x-ray image, preferably in standing, load-bearing position, a CT or spiral CT scan or an MRI scan or combinations thereof. A spiral CT scan may be advantageous over a standard CT scan due to its improved spatial resolution in z-direction in addition to x and y resolution. The articular

surface and shape as well as alignment information generated with the imaging test, along with any additional image groups and/or image assessment, evaluation, comparison and/or corrections, can be used to shape the surgical assistance device, to select the surgical assistance device from a library of different devices with pre-made shapes and sizes, or can be entered into the surgical assistance device and can be used to define the preferred location and orientation of saw guides or drill holes or guides for reaming devices or other surgical instruments. Intraoperatively, the surgical assistance device is applied to the tibial plateau and subsequently the femoral condyle(s) by matching its surface with the articular surface and/or any remaining failed implant components, or by attaching it to anatomic reference points on the bone or cartilage. The surgeon can then introduce a reamer or saw through the guides and prepare the joint for the implantation. By cutting the cartilage and bone along anatomically defined planes, a more reproducible placement of the implant can be achieved. This can ultimately result in improved postoperative results by optimizing biomechanical stresses applied to the implant and surrounding bone for the patient's anatomy and by minimizing axis mal-alignment of the implant. In addition, the surgical assistance device can greatly reduce the number of surgical instruments needed for total or unicompartmental knee arthroplasty. Thus, the use of one or more surgical assistance devices can help make joint arthroplasty more accurate, improve postoperative results, improve long-term implant survival, reduce cost by reducing the number of surgical instruments used. Moreover, the use of one or more surgical assistance device can help lower the technical difficulty of the procedure and can help decrease operating room ("OR") times.

Thus, surgical tools described herein can also be designed and used to control drill alignment, depth and width, for example when preparing a site to receive an implant. For example, the tools described herein, which typically conform to the joint surface and/or surfaces of the "failed implant," can provide for improved drill alignment and more accurate placement of any implant. An anatomically correct tool can be constructed by a number of methods and can be made of any material, preferably a substantially translucent and/or transparent material such as plastic, Lucite, silastic, SLA or the like, and typically is a block-like shape prior to molding.

FIG. **14**A depicts, in cross-section, an example of a mold **600** for use on the tibial surface having an upper surface **620**. The mold **600** contains an aperture **625** through which a surgical drill or saw can fit. The aperture guides the drill or saw to make the proper hole or cut in the underlying bone **610** as illustrated in FIGS. **11**B-D. Dotted lines **632** illustrate where the cut corresponding to the aperture will be made in bone.

FIG. **14**B depicts, a mold **608** suitable for use on the femur. As can be appreciated from this perspective, additional apertures are provided to enable additional cuts to the bone surface. The apertures **605** enable cuts **606** to the surface of the femur. The resulting shape of the femur corresponds to the shape of the interior surface of the femoral implant, typically as shown in FIG. **11**E. Additional shapes can be achieved, if desired, by changing the size, orientation and placement of the apertures. Such changes would be desired where, for example, the interior shape of the femoral component of the implant requires a different shape of the prepared femur surface.

Turning now to FIG. **15**, a variety of illustrations are provided showing a tibial cutting block and mold system. FIG. **15**A illustrates the tibial cutting block **2300** in conjunction with a tibia **2302** that has not been resected. In this depiction, the cutting block **2300** consists of at least two pieces. The first piece is a patient specific interior piece **2310** or mold that is designed on its inferior surface **2312** to mate, or substantially mate, with the existing geography of the patient's tibia **2302**. The superior surface **2314** and side surfaces **2316** of the first piece **2310** are configured to mate within the interior of an exterior piece **2320**. The reusable exterior piece **2320** fits over the interior piece **2310**. The system can be configured to hold the mold onto the bone.

The reusable exterior piece has a superior surface **2322** and an inferior surface **2324** that mates with the first piece **2310**. The reusable exterior piece **2320** includes cutting guides **2328**, to assist the surgeon in performing the tibial surface cut described above. As shown herein a plurality of cutting guides can be provided to provide the surgeon a variety of locations to choose from in making the tibial cut. If necessary, additional spacers can be provided that fit between the first patient configured, or molded, piece **2310** and the second reusable exterior piece, or cutting block, **2320**.

Clearly, the mold may be a single component or multiple components. In a preferred embodiment, one or more components are patient specific while other components such as spacers or connectors to surgical instruments are generic. In one embodiment, the mold can rest on portions of the joint on the articular surface or external to the articular surface (as well as on one or more surfaces or other features of the "failed implant"). Other surgical tools then may connect to the mold. For example, a standard surgical cut block as described for standard implants, for example in the knee the J&J PFC Sigma system, the Zimmer Nexgen system or the Stryker Duracon system, can be connected or placed on the mold. In this manner, the patient specific component can be minimized and can be made compatible with standard surgical instruments.

The mold may include receptacles for standard surgical instruments including alignment tools or guides. For example, a tibial mold for use in knee surgery may have an extender or a receptacle or an opening to receive a tibial alignment rod. In this manner, the position of the mold can be checked against the standard alignment tools and methods. Moreover, the combined use of molds and standard alignment tools including also surgical navigation techniques can help improve the accuracy of or optimize component placement in joint arthroplasty, such as hip or knee arthroplasty. For example, the mold can help define the depth of a horizontal tibial cut for placement of a tibial component. A tibial alignment guide, for example an extramedullary or intramedullary alignment guide, used in conjunction with a tibial mold can help find the optimal anteroposterior angulation, posterior slope, tibial slant, or varus-valgus angle of the tibial cut. The mold may be designed to work in conjuction with traditional alignment tools known in the art.

The mold may include markers, e.g. optoelectronic or radiofrequency, for surgical navigation. The mold may have receptacles to which such markers can be attached, either directly or via a linking member.

The molds can be used in combination with a surgical navigation system. They can be used to register the bones associated with a joint into the coordinate system of the surgical navigation system. For example, if a mold for a joint surface includes tracking markers for surgical navigation, the exact position and orientation of the bone can be detected by the surgical navigation system after placement of the mold in its unique position. This helps to avoid the time-consuming need to acquire the coordinates of tens to hundreds of points on the joint surface for registration.

Referring back to FIG. **15**A, the variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece **2320** such that it can achieve a cut that is perpendicular to the mechanical axis. Either the interior piece **2310** or the exterior piece **2320** can be formed out of any of the materials discussed above in Section II, or any other suitable material. Additionally, a person of skill in the art will appreciate that this disclosure is not limited to the two piece configuration described herein. The reusable exterior piece **2320** and the patient specific interior piece **2310** can be a single piece that is either patient specific (where manufacturing costs of materials support such a product) or is reusable based on a library of substantially defect conforming shapes developed in response to known or common tibial surface sizes and defects.

The interior piece **2310** is typically molded to the tibia including the subchondral bone and/or the cartilage. The surgeon will typically remove any residual meniscal tissue prior to applying the mold. Optionally, the interior surface **2312** of the mold can include shape information of portions or all of the menisci.

Turning now to FIG. **15**B-D, a variety of views of the removable exterior piece **2320**. The top surface **2322** of the exterior piece can be relatively flat. The lower surface **2324** which abuts the interior piece conforms to the shape of the upper surface of the interior piece. In this illustration the upper surface of the interior piece is flat, therefore the lower surface **2324** of the reusable exterior surface is also flat to provide an optimal mating surface.

A guide plate **2326** is provided that extends along the side of at least a portion of the exterior piece **2320**. The guide plate **2326** provides one or more slots or guides **2328** through which a saw blade can be inserted to achieve the cut desired of the tibial surface. Additionally, the slot, or guide, can be configured so that the saw blade cuts at a line perpendicular to the mechanical axis, or so that it cuts at a line that is perpendicular to the mechanical axis, but has a 4-7° slope in the sagittal plane to match the normal slope of the tibia.

Optionally, a central bore **2330** can be provided that, for example, enables a drill to ream a hole into the bone for the stem of the tibial component of the knee implant.

FIGS. **15**E-H illustrate the interior, patient specific, piece **2310** from a variety of perspectives. FIG. **15**E shows a side view of the piece showing the uniform superior surface **2314** and the uniform side surfaces **2316** along with the irregular inferior surface **2316**. The inferior surface mates with the irregular surface of the tibia **2302**. FIG. **15**F illustrates a superior view of the interior, patient, specific piece of the mold **2310**. Optionally having an aperture **2330**. FIG. **15**G illustrates an inferior view of the interior patient specific mold piece **2310** further illustrating the irregular surface which includes convex and concave portions to the surface, as necessary to achieve optimal mating with the surface of the tibia. FIG. **15**H illustrates cross-sectional views of the interior patient specific mold piece **2310**. As can be seen in the cross-sections, the surface of the interior surface changes along its length.

As is evident from the views shown in FIGS. **15**B and D, the length of the guide plate **2326** can be such that it extends along all or part of the tibial plateau, e.g. where the guide plate **2326** is asymmetrically positioned as shown in FIG. **15**B or symmetrical as in FIG. **15**D. If total knee arthroplasty is contemplated, the length of the guide plate **2326** typically extends along all of the tibial plateau. If unicompartmental arthroplasty is contemplated, the length of the guide plate typically extends along the length of the compartment that the surgeon will operate on. Similarly, if total knee arthroplasty is contemplated, the length of the molded, interior piece **2310** typically extends along all of the tibial plateau; it can include one or both tibial spines. If unicompartmental arthroplasty is contemplated, the length of the molded interior piece typically extends along the length of the compartment that the surgeon will operate on; it can optionally include a tibial spine.

Turning now to FIG. **15**I, an alternative embodiment is depicted of the aperture **2330**. In this embodiment, the aperture features lateral protrusions to accommodate using a reamer or punch to create an opening in the bone that accepts a stem having flanges.

FIGS. **15**J and M depict alternative embodiments of this disclosure designed to control the movement and rotation of the cutting block **2320** relative to the mold **2310**. As shown in FIG. **15**J a series of protrusions, illustrated as pegs **2340**, are provided that extend from the superior surface of the mold. As will be appreciated by those of skill in the art, one or more pegs or protrusions can be used without departing from the scope of the invention. For purposes of illustration, two pegs have been shown in FIG. **15**J. Depending on the control desired, the pegs **2340** are configured to fit within, for example, a curved slot **2342** that enables rotational adjustment as illustrated in FIG. **13**K or within a recess **2344** that conforms in shape to the peg **2340** as shown in FIG. **15**L. As will be appreciated by those of skill in the art, the recess **2344** can be sized to snugly encompass the peg or can be sized larger than the peg to allow limited lateral and rotational movement. The recess can be composed of a metal or other hard insert **544**.

As illustrated in FIG. **15**M the surface of the mold **2310** can be configured such that the upper surface forms a convex dome **2350** that fits within a concave well **2352** provided on the interior surface of the cutting block **2320**. This configuration enables greater rotational movement about the mechanical axis while limiting lateral movement or translation.

Other embodiments and configurations could be used to achieve these results without departing from the scope of the invention.

As will be appreciated by those of skill in the art, more than two pieces can be used, where appropriate, to comprise the system. For example, the patient specific interior piece **2310** can be two pieces that are configured to form a single piece when placed on the tibia. Additionally, the exterior piece **2320** can be two components. The first component can have, for example, the cutting guide apertures **2328**. After the resection using the cutting guide aperture **2328** is made, the exterior piece **2320** can be removed and a secondary exterior piece **2320'** can be used which does not have the guide plate **2326** with the cutting guide apertures **2328**, but has the aperture **2330** which facilitates boring into the tibial surface an aperture to receive a stem of the tibial component of the knee implant. Any of these designs could also feature the surface configurations shown in FIGS. **15**J-M, if desired.

FIG. **15**N illustrates an alternative design of the cutting block **2320** that provides additional structures **2360** to protect, for example, the cruciate ligaments, from being cut during the preparation of the tibial plateau. These additional structures can be in the form of indented guides **2360**, as shown in FIG. **15**N or other suitable structures.

FIG. **15**O illustrates a cross-section of a system having anchoring pegs **2362** on the surface of the interior piece **2310** that anchor the interior piece **2310** into the cartilage or meniscal area.

FIGS. **15**P AND Q illustrate a device **2300** configured to cover half of a tibial plateau such that it is unicompartmental.

FIG. **15**R illustrates an interior piece **2310** that has multiple contact surfaces **2312** with the tibia **2302**, in accordance with one embodiment of the invention. As opposed to one large contact surface, the interior piece **2310** includes a plurality of smaller contact surfaces **2312**. In various embodiments, the multiple contact surfaces **2312** are not on the sample plane and are at angles relative to each other to ensure proper positioning on the tibia **2302**. Two or three contact surfaces **2312** may be required to ensure proper positioning. In various embodiments, only the contact surfaces **2312** of the interior piece may be molded, the molds attached to the rest of the template using methodologies known in the art, such as adhesives. The molds may be removably attached to the template. It is to be understood that multiple contact surfaces **2312** may be utilized in template embodiments that include one or a plurality of pieces.

Turning now to FIG. **16**, a femoral mold system is depicted that facilitates preparing the surface of the femur such that the finally implanted femoral implant will achieve optimal mechanical and anatomical axis alignment.

FIG. **16**A illustrates the femur **2400** with a first portion **2410** of the mold placed thereon. In this depiction, the top surface of the mold **2412** is provided with a plurality of apertures. In this instance the apertures consist of a pair of rectangular apertures **2414**, a pair of square apertures **2416**, a central bore aperture **2418** and a long rectangular aperture **2420**. The side surface **2422** of the first portion **2410** also has a rectangular aperture **2424**. Each of the apertures is larger than the eventual cuts to be made on the femur so that, in the event the material the first portion of the mold is manufactured from a soft material, such as plastic, it will not be inadvertently cut during the joint surface preparation process. Additionally, the shapes can be adjusted, e.g., rectangular shapes made trapezoidal, to give a greater flexibility to the cut length along one area, without increasing flexibility in another area. As will be appreciated by those of skill in the art, other shapes for the apertures, or orifices, can be changed without departing from the scope of the invention.

FIG. **16**B illustrates a side view of the first portion **2410** from the perspective of the side surface **2422** illustrating the aperture **2424**. As illustrated, the exterior surface **2411** has a uniform surface which is flat, or relatively flat configuration while the interior surface **2413** has an irregular surface that conforms, or substantially conforms, with the surface of the femur.

FIG. **16**C illustrates another side view of the first, patient specific molded, portion **2410**, more particularly illustrating the irregular surface **2413** of the interior. FIG. **26**D illustrates the first portion **2410** from a top view. The center bore aperture **2418** is optionally provided to facilitate positioning the first piece and to prevent central rotation.

FIG. **16**D illustrates a top view of the first portion **2410**. The bottom of the illustration corresponds to an anterior location relative to the knee joint. From the top view, each of the apertures is illustrated as described above. As will be appreciated by those of skill in the art, the apertures can be shaped differently without departing from the scope of the invention.

Turning now to FIG. **16**E, the femur **2400** with a first portion **2410** of the cutting block placed on the femur and a second, exterior, portion **2440** placed over the first portion **2410** is illustrated. The second, exterior, portion **2440** features a series of rectangular grooves (**2442-2450**) that facilitate inserting a saw blade therethrough to make the cuts necessary to achieve the femur shape illustrated in FIG. **11**E. These grooves can enable the blade to access at a 90° angle to the surface of the exterior portion, or, for example, at a 45° angle. Other angles are also possible without departing from the scope of the invention.

As shown by the dashed lines, the grooves (**2442-2450**) of the second portion **2440**, overlay the apertures of the first layer.

FIG. **16**F illustrates a side view of the second, exterior, cutting block portion **2440**. From the side view a single aperture **2450** is provided to access the femur cut. FIG. **16**G is another side view of the second, exterior, portion **2440** showing the location and relative angles of the rectangular grooves. As evidenced from this view, the orientation of the grooves **2442**, **2448** and **2450** is perpendicular to at least one surface of the second, exterior, portion **2440**. The orientation of the grooves **2444**, **2446** is at an angle that is not perpendicular to at least one surface of the second, exterior portion **2440**. These grooves (**2444**, **2446**) facilitate making the angled chamfer cuts to the femur. FIG. **16**H is a top view of the second, exterior portion **2440**. As will be appreciated by those of skill in the art, the location and orientation of the grooves will change depending upon the design of the femoral implant and the shape required of the femur to communicate with the implant.

FIG. **16**I illustrates a spacer **2401** for use between the first portion **2410** and the second portion **2440**. The spacer **2401** raises the second portion relative to the first portion, thus raising the area at which the cut through groove **2424** is made relative to the surface of the femur. As will be appreciated by those of skill in the art, more than one spacer can be employed without departing from the scope of the invention. Spacers can also be used for making the tibial cuts. Optional grooves or channels **2403** can be provided to accommodate, for example, pins **2460** shown in FIG. **16**J.

Similar to the designs discussed above with respect to FIG. **15**, alternative designs can be used to control the movement and rotation of the cutting block **2440** relative to the mold **2410**. As shown in FIG. **16**J a series of protrusions, illustrated as pegs **2460**, are provided that extend from the superior surface of the mold. These pegs or protrusions can be telescoping to facilitate the use of molds if necessary. As will be appreciated by those of skill in the art, one or more pegs or protrusions can be used without departing from the scope of the invention. For purposes of illustration, two pegs have been shown in FIG. **16**J. Depending on the control desired, the pegs **2460** are configured to fit within, for example, a curved slot that enables rotational adjustment similar to the slots illustrated in FIG. **15**K or within a recess that conforms in shape to the peg, similar to that shown in FIG. **15**L and described with respect to the tibial cutting system. As will be appreciated by those of skill in the art, the recess **2462** can be sized to snugly encompass the peg or can be sized larger than the peg to allow limited lateral and rotational movement.

As illustrated in FIG. **16**K the surface of the mold **2410** can be configured such that the upper surface forms a convex dome **2464** that fits within a concave well **2466** provided on the interior surface of the cutting block **2440**. This configuration enables greater rotational movement about the mechanical axis while limiting lateral movement or translation.

In installing an implant, first the tibial surface is cut using a tibial block, such as those shown in FIG. **21**. The patient specific mold is placed on the femur. The knee is then placed in extension and spacers **2401**, such as those shown in FIG. **16**M, or shims are used, if required, until the joint optimal function is achieved in both extension and flexion. The spacers, or shims, are typically of an incremental size, e.g., 5 mm

thick to provide increasing distance as the leg is placed in extension and flexion. A tensiometer can be used to assist in this determination or can be incorporated into the mold or spacers in order to provide optimal results. The design of tensiometers are known in the art and are not included herein to avoid obscuring the invention. Suitable designs include, for example, those described in U.S. Pat. No. 5,630,820 to Todd issued May 20, 1997.

As illustrated in FIGS. **16**N (sagittal view) and **16**O (coronal view), the interior surface **2413** of the mold **2410** can include small teeth **2465** or extensions that can help stabilize the mold against the cartilage **2466** or subchondral bone **2467**.

3D guidance templates may be used to create more that one cut on the same and/or on the opposite articular surface or opposite articular bone, in accordance with an embodiment of the invention. These cuts may be cross-referenced with other cuts using one or more guidance template(s).

In accordance with one embodiment, the 3D guidance template(s) are utilized to perform more than one cut on the same articular side such as the femoral side of a knee joint. In another embodiment, a 3D guidance template may be utilized to cross reference surgical interventions on an opposing articular surface. In a knee, for example, the first articular surface can be the femoral surface. The opposing articular surface can be the tibial surface or the patella surface. In a hip, the first articular surface can be the acetabulum. The opposing articular surface or the opposing bone can be the proximal femur.

Thus, in a knee, a horizontal femur cut can be cross-referenced with an anterior or posterior femur cut or optionally also chamfer, oblique cuts. Similarly, a tibial horizontal cut can be cross-referenced with any tibial oblique or vertical cuts on the same articular side or surface.

In accordance with another embodiment, one or more femur cuts can be crossed-referenced with one or more tibial cuts. Or, in a hip, one or more acetabular cuts or surgical interventions can be cross-referenced with one or more femoral cuts or surgical interventions such as drilling, reaming or boring. Similarly, in a knee again, one or more femur cuts can be cross-referenced with one or more patella cuts. Any combination and order is possible.

The cross-referencing can occur via attachments or linkages including spacers or hinge or ratchet like devices from a first articular, bone, cartilage and/or implant surface, to a second articular, bone and/or cartilage surface. The resulting positioning of the cut on the opposing articular, bone or cartilage surface can be optimized by testing the cut for multiple pose angles or joint positions such as flexion, extension, internal or external rotation, abduction or adduction. Thus, for example, in a knee a distal femur cut can be performed with a mold. Via a linkage or an attachment, a tibial template may be attached thereto or to the cut or other surgical intervention, thus a cross-reference can be related from the femoral cut to a tibial cut or other surgical intervention. Cross-referencing from a first articular surface to a second articular surface via, without limitation, attachments or linkages to a template has the advantage of insuring an optimal alignment between the implant or other therapeutic device components of the first articular surface to that on a second articular surface. Moreover, by cross-referencing surgical interventions on a first surface to a second articular surface, improved efficiencies and time savings can be obtained with the resulted surgical procedure.

Cross-referencing the first, the second and, optionally a third or more articular surface, such as in a knee joint, may be performed with a single linkage or attachment or multiple linkages or attachments. A single pose angle or position of a joint or multiple pose angles or positions of a joint may be tested and optimized during the entire surgical intervention. Moreover, any resulting surgical interventions on the opposite, second articular surface, bone or cartilage may be further optimized by optionally cross-referencing to additional measurement tools such as standard alignment guides.

For example, in a knee joint, a 3D template may be utilized to perform one or more surgical interventions on the femoral side, such as a femoral cut. This can then be utilized via a linkage, an attachment or via indirect cross-referencing directly onto the site of surgical intervention, to guide a surgical intervention such as a cut of the tibial side. Prior to performing the surgical intervention on the tibial side, a traditional tibial alignment guide with cross-reference to the medial and lateral malleolus of the ankle turn may be used to optimize the position, orientation and/or depth and extent of the planned surgical intervention such as the cut. For example, cross-referencing to the femoral cut can aid in defining the relative superior inferior height of the tibial cut, while cross-referencing a tibial alignment guide can optionally be utilized to determine the slant of the cut in the interior posterior direction.

An exemplary system and methodology is now described in which a femoral template is used to make a cut on the femur, which is then cross-referenced to properly align a tibial template for making a cut on the tibial plateau. Initially, an electronic image(s) of the leg is obtained using imaging techniques elaborated in above-described embodiments. For example, a pre-operative CT scan of a patient's leg may be obtained to obtain electronic image data.

Image processing is then applied to the image data to derive, without limitation, relevant joint surfaces, axis, and/or cut planes. Image processing techniques may include, without limitation, segmentation and propagation of point clouds.

Relevant biomechanical and/or anatomical axis data may be obtained by identifying, for example, the central femoral head, central knee joint and center of the distal tibia. The cutting planes may then be defined based on at least one of these axis. For example, the tibial implant bearing surface may be defined as being perpendicular to the axis defined by the center of the tibial plateau **2496** and the center of the distal tibia **2497**, as illustrated in FIG. **16**P; the tibial implant's medial margin may project towards the femoral head, as illustrated in FIG. **16**Q; and the anterior to posterior slope of the tibia may be approximated by the natural anatomical slope (alternatively, excessive tibial slope may be corrected).

The tibial and femoral templates and implants may be designed based, at least in part, on the derived joint surfaces, axis and/or cut planes. FIGS. **16**R and **16**S show isometric views of a femoral template **2470** and a tibial template **2480**, respectively, in accordance with an embodiment of the invention. The femoral template **2470** has an interior surface that, in various embodiments, conforms, or substantially conforms, with the anatomic surface (bone and/or cartilage) of the femur **2475**. Furthermore, the interior surface of the femoral template may extend a desired amount around the anatomical bony surfaces of the condyle to further ensure proper fixation. The interior surface of the tibial cutting block **2480** may conform, or substantially conform to the surface (bone and/or cartilage) of the tibia **2481**.

In an exemplary use, the femoral template **2470** is placed on the femoral condyle **2475**, for example, when the knee is flexed. The femoral template **2470** may be fixed to the femoral condyle **2475** using, without limitation, anchoring screws/drill pins inserted through drill bushing holes **2471** and **2472**. The position of holes **2471** and **2472** on the condyle may be

the same used to anchor the final implant to the femur. In various embodiments, the holes **2471** and **2472** may include metal inserts/bushings to prevent degradation when drilling. Fixing the template **2470** to the femoral condyle **2475** advantageously prevents movement of the template during subsequent cutting or other surgical interventions thereby ensuring the accuracy of the resultant surgical cuts.

To assist in accurately positioning the femoral template **2470**, a femoral guide reference tool **2473** may be attached to the femoral template **2470**, as shown in FIG. **16**T. The femoral guide reference tool **2473** may, without limitation, attach to one of holes **2471** and **2472**. The femoral guide reference tool **2473** may reference off the tangential margin of the posterior condyle, and aid, for example, in correct anterior-posterior positioning of the femoral template **2470**.

Upon proper fixation of the femoral template **2470** to the femoral condyle **2475**, a cut to the femoral condyle is made using cut guide surface or element **2474**. The cut guide surface or element **2474** may be integral to the femoral template **2470**, or may be an attachment to the femoral template **2470**, with the attachment made of a harder material than the femoral template **2470**. For example, the cut guide surface or element **2474** may be a metal tab that slides onto the femoral template **2470**, which may be made, without limitation, of a softer, plastic material.

Upon making the femoral cut and removing the femoral template **2475**, a sample implant template **2476** (not the final implant) is optionally positioned on the condyle, as shown in FIG. **16**U, in accordance with an embodiment of the invention. The sample implant template **2474** may be attached to the condyle by using without limitation, anchoring screws/drill pins inserted through the same holes used to anchor the final implant to the femur.

The sample implant template **2476** includes an attachment mechanism **2494** for attaching the tibial template **2480**, thereby cross-referencing the placement of the distal tibial cut with respect to the femoral cut/implant's placement. The attachment mechanism **2494** may be, without limitation, a boss, as shown in FIG. **16**U, or other attachment mechanism known in the art, such as a snap-fit mechanism. Note that in alternative embodiments, a sample implant template **2476** is not required. For example, the tibial template **2480** may attach directly to the femoral template **2470**. However, in the subject embodiment, the drill bushing features of the femoral template **2475** will interfere with the knee going into extension, preventing the tibial cut.

In illustrative embodiments, the thickness of the sample implant template **2476** may not only include the thickness of the final femoral implant, but may include an additional thickness that corresponds to a preferred joint space between tibial and femoral implants. For example, the additional thickness may advantageously provide a desired joint space identified for proper ligament balancing or for flexion, extension, rotation, abduction, adduction, anteversion, retroversion and other joint or bone positions and motion.

FIG. **16**V is an isometric view of the interior surface of the sample implant template **2476**, in accordance with an embodiment of the invention. In various embodiments, the femoral implant often rests on subchondral bone, with the cartilage being excised. In embodiments where the sample implant template **2474** extends beyond the dimensions of the femoral implant such that portions of the sample implant template **2476** rests on cartilage, an offset **2477** in the interior surface of the sample implant template **2476** may be provided.

FIG. **16**W is an isometric view of the tibial template **2480** attached to the sample implant **2476** when the knee is in extension, in accordance with an embodiment of the invention. A crosspin **2478** inserted through boss **2494** fixes the tibial template **2480** to the sample implant template **2474**. Of course, other attachment mechanisms may be used, as described above. In preferred embodiments, the tibial template **2480** may also be fixed to the tibia **2481** using, without limitation, anchoring screws/drill pins inserted through drill bushing hole **2479**. In various embodiments, the holes **2479** include metal inserts (or other hard material) to prevent degradation when drilling. As with the femoral template **2475**, the cut guide surface or element of the tibial template **2480** may be integral to the tibial template **2475**, or may be an attachment to the tibial template **2480**, the attachment made of a harder material than the tibial template **2480**. Upon fixing the position of the tibial template **2480**, the cut guide of the tibial template **2475** assists in guiding the desired cut on the tibia.

FIG. **16**X shows a tibial template **2490** that may be used, after the tibial cut has been made, to further guide surgical tools in forming anchoring apertures in the tibia for utilization by the tibial implant (e.g., the tibial implant may include pegs and/or keels that are used to anchor the tibial implant into the tibia), in accordance with an embodiment of the invention. The outer perimeter of a portion of the tibial template **2490** may mimic the perimeter of the tibial implant. Guide apertures in the tibial template **2490** correspond to the tibial implants fixation features. A portion of the tibial template **2490** conforms to, without limitation, the anterior surface of the tibia to facilitate positioning and anchoring of the template **2490**.

FIG. **16**Y shows a tibial implant **2425** and femoral implant **2426** inserted onto the tibia and femur, respectively, after the above-described cuts have been made, in accordance with an embodiment of the invention.

Thus, the tibial template **2480** used on the tibia can be cross-referenced to the femoral template **2476**, femoral cut and/or sample implant **2474**. Similarly, in the hip, femoral templates can be placed in reference to an acetabular mold or vice versa. In general, when two or more articular surfaces will be repaired or replaced, a template can be placed on one or more of them and surgical procedures including cutting, drilling, sawing or rasping can be performed on the other surface or other surfaces in reference to said first surface(s).

In illustrative embodiments, three-dimensional guidance templates may be utilized to determine an optimized implant rotation. Examples are provided below with reference to the knee, however it is to be understood that optimizing implant rotation may be applied other joints as well.

Femoral Rotation:

The optimal rotation of a femoral component or femoral implant for a uni-compartmental, patello femoral replacement or total knee replacement may be ascertained in a number of different ways. Implant rotation is typically defined using various anatomic axes or planes. These anatomic axes may include, without limitation, the transepicondylar axis; the Whiteside line, i.e. the trochlea anteroposterior axis, which is typically perpendicular to at least one of the cuts; and/or the posterior condylar axis. Another approach for optimizing femoral component rotation is a so-called balancing gap technique. With the balancing gap technique, a femoral cut is made parallel to the tibia, i.e. the tibia is cut first typically. Prior to performing the femoral cut, the femoral cut plate is optimized so that the medial and lateral ligament and soft tissue tension are approximately equal.

By measuring the relevant anatomic axis or planes, the optimal implant rotation may be determined. The measurement may be factored into the shape, position or orientation of

the 3D guidance template, in accordance with an embodiment of the invention. Any resultant surgical interventions including cuts, drilling, or sawings are then made incorporating this measurement, thereby achieving an optimal femoral component rotation.

Moreover in order to achieve an optimal balancing, the rotation of the template may be changed so that the cuts are parallel to the tibial cut with substantially equal tension medially and laterally applied.

Tibial Rotation:

A 3D guidance template may also be utilized to optimize tibial component rotation for uni-compartmental or total knee replacements, in accordance with an embodiment of the invention. Tibial component rotation may be measured using a number of different approaches known in the art. In one example of a tibial component rotation measurement, the anteroposterior axis of the tibia is determined. For a total knee replacement, the tibial component can be placed so that the axis of the implant coincides with the medial one-third of the tibial tuberosity. This approach works well when the tibia is symmetrical.

In another embodiment, the symmetrical tibial component is placed as far as possible posterolateral and externally rotated so that the posteromedial corner of the tibial plateau is uncovered to an extent of between three (3) and five (5) millimeters.

The above examples are only representative of the different approaches that have been developed in the literature. Clearly, other various anatomic axis, plane and area measurements may be performed in order to optimize implant rotation.

In illustrative embodiments, these measurements may be factored into the design of a 3D guidance template and the position, shape or orientation of the 3D guidance template may be optimized utilizing this information. Thus, any subsequent surgical intervention such as cutting, sawing and/or drilling will result in an optimized implant rotation, for example, in the horizontal or in a near horizontal plane.

Turning now to FIG. **17**, a variety of illustrations are provided showing a patellar cutting block and mold system. FIGS. **17**A-C illustrates the patellar cutting block **2700** in conjunction with a patella **2702** that has not been resected. In this depiction, the cutting block **2700** can consist of only one piece or a plurality of pieces, if desired. The inner surface **2703** is patient specific and designed to mate, or substantially mate, with the existing geography of the patient's patella **2702**. Small openings are present **2707** to accept the saw. The mold or block can have only one or multiple openings. The openings can be larger than the saw in order to allow for some rotation or other fine adjustments. FIG. **17**A is a view in the sagittal plane S. The quadriceps tendon **2704** and patellar tendon **2705** are shown.

FIG. **17**B is a view in the axial plane A. The cartilage **2706** is shown. The mold can be molded to the cartilage or the subchondral bone or combinations thereof. FIG. **17**C is a frontal view F of the mold demonstrating the opening for the saw **2707**. The dashed line indicates the relative position of the patella **2702**.

FIGS. **17**D (sagittal view) and E (axial view) illustrate a patellar cutting block **2708** in conjunction with a patella **2702** that has not been resected. In this depiction, the cutting block **2708** consists of at least two pieces. The first piece is a patient specific interior piece **2710** or mold that is designed on its inferior surface **2712** to mate, or substantially mate, with the existing geography of the patient's patella **2702**. The posterior surface **2714** and side surfaces **2716** of the first piece **2710** are configured to mate within the interior of an exterior piece **2720**. The reusable exterior piece **2720** fits over the interior piece **2710** and holds it onto the patella. The reusable exterior piece has an interior surface **2724** that mates with the first piece **2710**. The reusable exterior piece **2720** includes cutting guides **2707**, to assist the surgeon in performing the patellar surface cut. A plurality of cutting guides can be provided to provide the surgeon a variety of locations to choose from in making the patellar cut. If necessary, additional spacers can be provided that fit between the first patient configured, or molded, piece **2710** and the second reusable exterior piece, or cutting block, **2720**.

The second reusable exterior piece, or cutting block, **2720**, can have grooves **2722** and extensions **2725** designed to mate with surgical instruments such as a patellar clamp **2726**. The patellar clamp **2726** can have ring shaped graspers **2728** and locking mechanisms, for example ratchet-like **2730**. The opening **2732** in the grasper fits onto the extension **2725** of the second reusable exterior piece **2720**. Portions of a first portion of the handle of the grasper can be at an oblique angle **2734** relative to the second portion of the handle, or curved (not shown), in order to facilitate insertion. Typically the portion of the grasper that will be facing towards the intra-articular side will have an oblique or curved shaped thereby allowing a slightly smaller incision.

The variable nature of the interior piece facilitates obtaining the most accurate cut despite the level of disease of the joint because it positions the exterior piece **2720** in the desired plane. Either the interior piece **2710** or the exterior piece **2720** can be formed out of any of the materials discussed above in Section II, or any other suitable material. Additionally, a person of skill in the art will appreciate that this disclosure is not limited to the two piece configuration described herein. The reusable exterior piece **2720** and the patient specific interior piece **2710** can be a single piece that is either patient specific (where manufacturing costs of materials support such a product) or is reusable based on a library of substantially defect conforming shapes developed in response to known or common tibial surface sizes and defects.

The interior piece **2710** is typically molded to the patella including the subchondral bone and/or the cartilage.

From this determination, an understanding of the amount of space needed to balance the knee is determined and an appropriate number of spacers is then used in conjunction with the cutting block and mold to achieve the cutting surfaces and to prevent removal of too much bone. Where the cutting block has a thickness of, for example, 10 mm, and each spacer has a thickness of 5 mm, in preparing the knee for cuts, two of the spacers would be removed when applying the cutting block to achieve the cutting planes identified as optimal during flexion and extension. Similar results can be achieved with ratchet or jack like designs interposed between the mold and the cut guide.

vii. Hip Joint

Turning now to FIG. **18**, a variety of views showing sample mold and cutting block systems for use in the hip joint are shown. FIG. **18**A illustrates femur **2510** with a mold and cutting block system **2520** placed to provide a cutting plane **2530** across the femoral neck **2512** to facilitate removal of the head **2514** of the femur and creation of a surface **2516** for the hip ball prosthesis.

FIG. **18**B illustrates a top view of the cutting block system **2520**. The cutting block system **2520** includes an interior, patient specific, molded section **2524** and an exterior cutting block surface **2522**. The interior, patient specific, molded section **2524** can include a canal **2526** to facilitate placing the interior section **2524** over the neck of the femur. As will be appreciated by those of skill in the art, the width of the canal will vary depending upon the rigidity of the material used to

make the interior molded section. The exterior cutting block surface **2522** is configured to fit snugly around the interior section. Additional structures can be provided, similar to those described above with respect to the knee cutting block system, that control movement of the exterior cutting block **2524** relative to interior mold section **2522**, as will be appreciated by those of skill in the art. Where the interior section **2524** encompasses all or part of the femoral neck, the cutting block system can be configured such that it aids in removal of the femoral head once the cut has been made by, for example, providing a handle **2501**.

FIG. **18**C illustrates a second cutting block system **2550** that can be placed over the cut femur to provide a guide for reaming after the femoral head has been removed using the cutting block shown in FIG. **18**A. FIG. **18**D is a top view of the cutting block shown in FIG. **18**C. As will be appreciated by those of skill in the art, the cutting block shown in FIG. **18**C-D, can be one or more pieces. As shown in FIG. **18**E, the aperture **2552** can be configured such that it enables the reaming for the post of the implant to be at a 90° angle relative to the surface of femur. Alternatively, as shown in FIG. **18**F, the aperture **2552** can be configured to provide an angle other than 90° for reaming, if desired.

FIGS. **19**A (sagittal view) and **29**B (frontal view, down onto mold) illustrates a mold system **2955** for the acetabulum **2957**. The mold can have grooves **2959** that stabilize it against the acetabular rim **2960**. Surgical instruments, e.g. reamers, can be passed through an opening in the mold **2956**. The side wall of the opening **2962** can guide the direction of the reamer or other surgical instruments. Metal sleeves **2964** can be inserted into the side wall **2962** thereby protecting the side wall of the mold from damage. The metal sleeves **2964** can have lips **2966** or overhanging edges that secure the sleeve against the mold and help avoid movement of the sleeve against the articular surface.

FIG. **19**C is a frontal view of the same mold system shown in FIGS. **19**A and **19**B. A groove **2970** has been added at the 6 and 12 o'clock positions. The groove can be used for accurate positioning or placement of surgical instruments. Moreover, the groove can be useful for accurate placement of the acetabular component without rotational error. Someone skilled in the art will recognize that more than one groove or internal guide can be used in order to not only reduce rotational error but also error related to tilting of the implant. As seen FIG. **19**D, the implant **2975** can have little extensions **2977** matching the grooves thereby guiding the implant placement. The extensions **2977** can be a permanent part of the implant design or they can be detachable. Note metal rim **2979** and inner polyethylene cup **2980** of the acetabular component.

FIG. **19**D illustrates a cross-section of a system where the interior surface **2960** of the molded section **2924** has teeth **2962** or grooves to facilitate grasping the neck of the femur.

Various steps may be performed in order to design and make 3D guidance templates for hip implants, in accordance with an embodiment of the invention.

For example, in an initial step, a discrepancy in the length of the left leg and right leg may be determined, for example, in millimeters. Leg length discrepancy may be determined, for example, using standing x-rays, typically including the entire leg but also cross-sectional imaging modalities such as CT or MRI.

A CT scout scan may be utilized to estimate leg length. Alternatively, select image slices through the hip and ankle joint may be utilized to estimate leg length either using CT or MRI.

Pre-operative planning is then performed using the image data (including final image data assessed, evaluated, cross-referenced, derived and/or corrected from image groups as previously described). A first 3D guidance template is designed to rest on the femoral neck. FIG. **33** shows an example of an intended site **4300** for placement of a femoral neck mold for total hip arthroplasty. (In a similar manner, an existing "failed implant" component may be utilized as an alignment surface or surfaces, alone or in combination with anatomical surfaces, for preparation of the joint to receive a "revision implant.") A cut or saw plane integrated into this template can be derived. The position, shape and orientation of the 3D guidance mold or jig or template may be determined on the basis of anatomical axis such as the femoral neck axis, the mechanical axis and/or also any underlying leg length discrepancy (FIG. **29**). Specifically, the superoinferior cut or saw guide height can be adapted to account for leg length discrepancy. For example, if the left leg is five (5) millimeters shorter than the right leg, then the cut height can be moved by five (5) millimeters to account for this difference. The femoral neck cut height ultimately determines the position of the femoral stem. Thus, in this manner, using this type of pre-operative planning, the femoral neck cut height can be optimized using a 3D guidance template.

FIG. **29** is a flow diagram of a method wherein measurement of leg length discrepancy can be utilized to determine the optimal cut height of the femoral neck cut for total hip arthroplasty. Initially, imaging is performed, e.g. CT and/or MRI, through, without limitation, the hip, knee and ankle joint, step **3902**. Leg length discrepancy is determined, using the imaging data obtained, step **3904**. The preferred implant size may then be optionally determined, step **3906**. The preferred femoral neck cut position is determined based, at least in part, on correcting the leg length discrepancy for optimal femoral component placement.

FIG. **34** shows another example of a femoral neck mold **4400** with handle **4410** and optional slot **4420**.

Acetabulum:

In the acetabulum, the position and orientation of the acetabular component or acetabular cup is also critical for the success of hip surgery. For example, the lowest portion of the acetabular cup may be placed so that it is five (5) millimeters lateral to an anatomic landmark on a pelvic x-ray coinciding with the inferior border of the radiographic tear drop. If the acetabular component is, for example, placed too far superiorly, significant bone may be lost.

Placing the acetabular component using the 3D guidance template may include, for example, the following steps:

Step One: Imaging, e.g. using optical imaging methods, CT or MRI.

Step Two: Determining the anterior rotation of the acetabulum and the desired rotation of the acetabular cup.

Step Three: Find best fitting cup size.

Step Four: Determine optimal shape, orientation and/or position of 3D guidance template.

The template may be optionally designed to rest primarily on the margin of the acetabular fossa. In this manner, it is possible to ream through the template.

FIG. **35** shows an example of a posterior acetabular approach for total hip replacement. Tissue retractors **4510** are in place. The acetabular fosse is visible **4520**.

FIG. **36** shows an example of a guidance mold used for reaming the site for an acetabular cup. The mold **4600** can be optionally attached to a generic frame **4610**. A guide for the reamer is shown **4620**. The reamer **4630** or the mold can have

optional stops **4640**. In this example, the stops **4640** are attached to the reamer **4630** and engage the guide **4620** for the reamer.

For purposes of reaming, the template may be fixed to the pelvis, for example, using metal spikes or K-wires. The template may also have a grip for fixing it to the bone. Thus, a surgeon may optionally press the template against the bone while a second surgeon will perform the reaming through the opening in the template. The grip or any stabilizers can extend laterally, and optionally serve as tissue retractors, keeping any potentially interfering soft tissue out of the surgical field. The template may also include stoppers **4640** to avoid over penetration of the reamer. These stoppers may be designed in the form of metal stops defining the deepest penetration area for the peripheral portion or other portions of the reamer. Optionally, the template may also taper and decrease in inner radius thereby creating a stop once the reamer once the reaches the innermost portion of the template. Any stop known in the art can be used. The imaging test can be used to design or shape the mold in a manner that will help achieve the optimal reaming depth. The stops can be placed on the mold or reamer in reference to the imaging test in order to achieve the optional reaming depth.

A 3D guidance template may be utilized to optimize the anteversion of the acetabular cup. For example, with the posteriolateral approach, typically an anteversion of forty to forty-five degrees is desired in both males and females. With an anterolateral approach, zero degrees anteversion may be desired. Irrespective of the desired degree of anti-version, the shape, orientation and/or position of the template may be optimized to include the desired degree of anteversion.

Similarly, on the femoral side, the 3D guidance template may be optimized with regard to its shape, orientation and position in order to account for neutral, varus or valgus position of the femoral shaft. A 3D guidance template may also be utilized to optimize femoral shaft anteversion.

Thus, after a first template has been utilized for performing the femoral neck cut and a second template has been utilized for performing the surgical intervention on the acetabular side, a third template may optionally be utilized to be placed onto the femoral cut.

Optionally, modular hip implant components may be utilized such as a modular stem. Such modular designs can be helpful in further optimizing the resultant femoral anteversion by selecting, for example, different stem shapes.

In another embodiment, the surgeon may perform a femur first technique wherein a first cut is applied to the femur using a first 3D guidance mold. Optionally, the broach in the cut femoral shaft may be left in place. Optionally, a trial implant head may be applied to the broach. The trial implant head may be variable in radius and superoinferior diameter and may be utilized to determine the optimal soft tissue tension. Optionally, the trial head may also be utilized to determine the acetabular cup position wherein said acetabular cup position is derived on the basis of the femoral cut. Thus, the acetabular position can be optionally derived using the opposite articular surface. In a reverse acetabulum first technique, the acetabulum can be prepared first and, using soft tissue balancing techniques, the femoral component can be placed in reference to the acetabular component. Optionally, the femoral cut may even be placed intentionally too proximal and is subsequently optimized by measuring soft tissue tension utilizing various trial heads with the option to then change the height of the optimal femoral cut.

Positioning of Template

In an illustrative embodiment, in order to make a guidance template reliably and reproducibly, a portion of the joint is identified in a first step wherein said portion of the joint has not been altered by the arthritic process. In a second step, the surface or a point cloud of said portion of the joint is derived, and may, optionally, be used to derive a virtual 3D model and, in a third step, to generate a physical model as part of the guidance template. Using a portion of the joint that has not been altered by the arthritic process can advantageously improve the reproducibility and the accuracy of the resultant mold or jig or template. In a similar manner, the use of existing feature(s) of a "failed implant" may be useful for alignment of the template as described herein.

The step of identifying said portion of the joint may be visual, semiautomatic or fully automatic. Anatomic models may assist in the process. Anatomic reference standards may be utilized.

As known in the art, various methods for image segmentation may be used to derive the point cloud or the surface. Suitable algorithms include, for example, but are not limited to snakes, live wire, thresholding, active contours, deformable models and the like. Artificial neural networks may be employed to improve the accuracy of the molds.

In another embodiment, the current mechanical axis may determined or estimated in a first step. In a second step, the desired mechanical axis is determined. In a third step adjustments, for example via change in slot position or position for openings for saws and drills and the like, may be made to alter the cut or drill position in order to correct the mechanical axis in a fourth step. In a fifth step, the position of the slot or openings for saws and drills and the like may be adjusted for ligament balancing and/or for optimizing flexion and extension gap. This adjustment may be performed in the 3D model prior to the manufacturing process. Alternatively, adjustments may be made intraoperatively, for example via spacers or ratchet like devices or pins to allow for some degree of rotation.

In another embodiment, at least a portion of the surface of the mold or jig or template is derived from a portion of the joint and/or implant that is affected by the arthritic process. Optionally, adjustment means can be performed, for example via the software, to simulate a normal shape. The difference between the actual shape and the adjusted shape can be utilized to optimize the position of the slots or openings in the mold or template or jig.

In a preferred embodiment, at least a portion of the surface of the mold or jig or template that is in contact with the joint may be derived from a portion of the joint that is affected by the arthritic process and a portion of the joint that has not been altered by the arthritic process. By spanning both normal and diseased portions of the joint, the interface between normal and diseased portions of the joint is included in the surface of the mold. The interface between normal and diseased portions of the joint is typically characterized by a sudden change in contour or shape, e.g. a reduction in cartilage thickness, a change in subchondral bone contour, a cyst or a bone spur. This change in joint contour or shape provides additional reference points for accurately placing the mold or jig or template. In addition, this change in joint contour or shape provides also additional stabilization or fixation of the mold or jig or template on the surface of the joint, in particular while performing surgical interventions such as cutting, drilling or sawing.

The design is proposed such that the guide is molded to precisely fit the anatomy of the articular surface of the patella for each patient, thus providing precise location of the patella planing needed. As will be appreciated by those of skill in the art, while an exact or precise fit is desired, deviations from a

precise fit can occur without departing from the scope of the invention. Thus, it is anticipated that a certain amount of error in the design can be tolerated.

B. Small, Focal Cartilage Defect

After identification of the cartilage defect and marking of the skin surface using the proprietary U-shaped cartilage defect locator device as described herein, a 3 cm incision is placed and the tissue retractors are inserted. The cartilage defect is visualized.

A first Lucite block matching the 3D surface of the femoral condyle is placed over the cartilage defect. The central portion of the Lucite block contains a drill hole with an inner diameter of, for example, 1.5 cm, corresponding to the diameter of the base plate of the implant. A standard surgical drill with a drill guide for depth control is inserted through the Lucite block, and the recipient site is prepared for the base component of the implant. The drill and the Lucite block are then removed.

A second Lucite block of identical outer dimensions is then placed over the implant recipient site. The second Lucite block has a rounded, cylindrical extension matching the size of the first drill hole (and matching the shape of the base component of the implant), with a diameter 0.1 mm smaller than the first drill hole and 0.2 mm smaller than that of the base of the implant. The cylindrical extension is placed inside the first drill hole.

The second Lucite block contains a drill hole extending from the external surface of the block to the cylindrical extension. The inner diameter of the second drill hole matches the diameter of the distal portion of the fin-shaped stabilizer strut of the implant, e.g. 3 mm. A drill, e.g. with 3 mm diameter, with a drill guide for depth control is inserted into the second hole and the recipient site is prepared for the stabilizer strut with a four fin and step design. The drill and the Lucite block are then removed.

A plastic model/trial implant matching the 3-D shape of the final implant with a diameter of the base component of 0.2 mm less than that of the final implant and a cylindrical rather than tapered strut stabilizer with a diameter of 0.1 mm less than the distal portion of the final implant is then placed inside the cartilage defect. The plastic model/trial implant is used to confirm alignment of the implant surface with the surrounding cartilage. The surgeon then performs final adjustments.

The implant is subsequently placed inside the recipient site. The anterior fin of the implant is marked with red color and labeled "A." The posterior fin is marked green with a label "P" and the medial fin is color coded yellow with a label "M." The Lucite block is then placed over the implant. A plastic hammer is utilized to advance the implant slowly into the recipient site. A press fit is achieved with help of the tapered and four fin design of the strut, as well as the slightly greater diameter (0.1 mm) of the base component relative to the drill hole. The Lucite block is removed. The tissue retractors are then removed. Standard surgical technique is used to close the 3 cm incision. The same procedure described above for the medial femoral condyle can also be applied to the lateral femoral condyle, the medial tibial plateau, the lateral tibial plateau and the patella. Immediate stabilization of the device can be achieved by combining it with bone cement if desired.

IV. Kits

Also described herein are kits comprising one or more of the methods, systems and/or compositions described herein. In particular, a kit can include one or more of the following: instructions (methods) of obtaining electronic images; systems or instructions for evaluating electronic images; one or more computer means capable of analyzing or processing the electronic images; and/or one or more surgical tools for implanting an articular repair system. For example, a kit may include an articular repair system (e.g., one or more implant components) designed, made, selected, engineered or adapted for a patient, and one or more single-use surgical tools that facilitate placement of the articular repair system into the patient.

The following examples are included to more fully illustrate the present invention. Additionally, these examples provide preferred embodiments of this disclosure and are not meant to limit the scope thereof.

EXAMPLE 1

Design and Construction of a Three-Dimensional Articular Repair System

Areas of cartilage are imaged as described herein to detect areas of cartilage loss and/or diseased cartilage. The margins and shape of the cartilage and subchondral bone adjacent to the diseased areas are determined. The thickness of the cartilage is determined. The size of the articular repair system is determined based on the above measurements. In particular, the repair system is either selected (based on best fit) from a catalogue of existing, pre-made implants with a range of different sizes and curvatures or custom-designed using CAD/CAM technology. The library of existing shapes is typically on the order of about 30 sizes.

The implant is a chromium cobalt implant. The articular surface is polished and the external dimensions slightly greater than the area of diseased cartilage. The shape is adapted to achieve perfect or near perfect joint congruity utilizing shape information of surrounding cartilage and underlying subchondral bone. Other design features of the implant can include: a slanted (60- to 70-degree angle) interface to adjacent cartilage; a broad-based base component for depth control; a press fit design of base component; a porous coating of base component for ingrowth of bone and rigid stabilization; a dual peg design for large defects implant stabilization, also porous coated; a single stabilizer strut with tapered, four fin and step design for small, focal defects, also porous coated; and a design applicable to femoral resurfacing (convex external surface) and tibial resurfacing (concave external surface).

EXAMPLE 2

Minimally Invasive, Arthroscopically Assisted Surgical Technique

The articular repair systems are inserted using arthroscopic assistance. The device does not require the 15 to 30 cm incision utilized in unicompartmental and total knee arthroplasties. The procedure is performed under regional anesthesia, typically epidural anesthesia. The surgeon can apply a tourniquet on the upper thigh of the patient to restrict the blood flow to the knee during the procedure. The leg is prepped and draped in sterile technique. A stylette is used to create two small 2 mm ports at the anteromedial and the anterolateral aspect of the joint using classical arthroscopic technique. The arthroscope is inserted via the lateral port. The arthroscopic instruments are inserted via the medial port. The cartilage defect is visualized using the arthroscope. A cartilage defect locator device is placed inside the diseased cartilage. The probe has a U-shape, with the first arm touching the center of the area of diseased cartilage inside the joint and the second arm of the U remaining outside the joint. The second arm of the U indicates the position of the cartilage relative to

the skin. The surgeon marks the position of the cartilage defect on the skin. A 3 cm incision is created over the defect. Tissue retractors are inserted and the defect is visualized.

A translucent Lucite block matching the 3D shape of the adjacent cartilage and the cartilage defect is placed over the cartilage defect. For larger defects, the Lucite block includes a lateral slot for insertion of a saw. The saw is inserted and a straight cut is made across the articular surface, removing an area slightly larger than the diseased cartilage. The center of the Lucite block contains two drill holes with a 7.2 mm diameter. A 7.1 mm drill with drill guide controlling the depth of tissue penetration is inserted via the drill hole. Holes for the cylindrical pegs of the implant are created. The drill and the Lucite block are subsequently removed.

A plastic model/trial implant of the mini-repair system matching the outer dimensions of the implant is then inserted. The trial implant is utilized to confirm anatomic placement of the actual implant. If indicated, the surgeon can make smaller adjustments at this point to improve the match, e.g. slight expansion of the drill holes or adjustment of the cut plane.

The implant is then inserted with the pegs pointing into the drill holes. Anterior and posterior positions of the implant are color-coded; specifically the anterior peg is marked with a red color and a small letter "A", while the posterior peg has a green color and a small letter "P". Similarly, the medial aspect of the implant is color-coded yellow and marked with a small letter "M" and the lateral aspect of the implant is marked with a small letter "L". The Lucite block is then placed on the external surface of the implant and a plastic hammer is used to gently advance the pegs into the drill holes. The pegs are designed to achieve a press fit.

The same technique can be applied in the tibia. The implant has a concave articular surface matching the 3D shape of the tibial plateau. Immediate stabilization of the device can be achieved by combining it with bone cement if desired.

EXAMPLE 3

"Failed Implant" Assisted Knee Technique

Example 3 depicts one embodiment of a revision system, method and devices contemplated by the present invention. In this embodiment, a total knee implant is experiencing failure or impending failure for any number of reasons, and requires surgical removal and revision to a replacement total knee implant. While the current embodiment contemplates removal and replacement of all implant components, it should be understood that a partial component replacement and/or implantation, either of one side (i.e., all of the tibial components) of an implant, as well as replacement and/or implantation of individual failed or failing components of the implant, are contemplated by the present invention.

Initially, the "failed implant" will be assessed and diagnosed. This process typically includes non-invasive imaging of the implant and the patient's anatomy, usually in an attempt to determine the condition of the implant and/or joint as well as to identify any discernable failure mode (i.e., did the implant break, did cement loosen, or has the underlying anatomical structure degraded and the implant has loosened). The non-invasive imaging will desirably create 2 or 3 dimensional images and/or image databases of the joint and the failed implant components (the "failed implant" images).

In addition to the "failed implant" images, it is desirable, but not absolutely necessary in all embodiments, to obtain additional image sets from the patient's history (see Table 1 for various exemplary image types). If desired, the images can be normalized, assessed, evaluated, cross-referenced and/or corrected, or any combination thereof, as previous described. It should be understood that such manipulation of the images may be conducted in virtually any order, with various steps following other steps (i.e., images may be cross-referenced and then corrected, or may be corrected and then cross-referenced, etc.). Similarly, the various image processing steps may be repeated as necessary or desired, such as normalizing an image, then cross-referencing and/or correcting an image, and then normalizing the processed image, etc.

Once an acceptable and/or accurate view of the "failed implant" and the underlying joint anatomy have been ascertained and/or modeled as described, the resulting implant and joint image information (the "generated image information") may be used to plan the revision surgery. This generated information may be utilized to create a patient-specific revision implant and/or components, and/or may be used to choose a "best fit" revision implant from a series of pre-manufactured and/or pre-designed implant components as described herein.

The generated Information may also be highly useful in assessing the failure and/or success potential of the revision implant, especially where such information reflects joint condition over the course of the treatment over time. Specifically, the generated information may identify areas of insufficient support structure and/or areas of high wear and/or stress that may lead to premature failure or other undesirable wear of the revision implant. If desired, this information may be utilized to modify the implant in some manner (i.e., reinforce areas of higher stress and/or wear or reduce the size/thickness of areas that experience lower stresses or wear), or may be utilized to modify the implantation procedure and/or implant components.

In a similar manner, the generated information may be utilized to determine if augments or other accessory structures (which may or may not be secured to the revision implant and/or the underlying anatomical support structure) are necessary or needed for placement of surgical tool s and the revision implant. For example, the various imaging and processing techniques may reveal significant osteolysis of the anatomical support structure. Desirably, this osteolysis will be accounted for during the design and/or selection of revision components, allowing the determination of augments (i.e., blocks and/or wedges, etc.) require for proper implant placement. If desired, additional augments of differing sizes and/or shapes may also be provided to account for any inaccuracies or unanticipated "real world" conditions experienced (i.e., significantly less bone support than anticipated, extremely poor bone quality precluding use as support structure, localized bone disease or infection, fracture or "bonding" of support structures to the failed implant during removal, etc.) when the "failed implant" is removed and the actual anatomical support structure is revealed. Similar augments may be provided for use with the various surgical tools and molds of the present invention, assisting tint the proper alignment and placement of bone cuts, burring, reaming, drilling, etc.

Once a desired revision implant has been chosen or designed, the various generated information may be utilized to create surgical tools and/or molds for assisting with the preparation of the revision implant site. Desirably, these tools will incorporate readily accessible anatomical and/or "failed implant" landmarks to assist with the alignment and placement of the subsequent revision implant. In at least one embodiment, the tool includes at least one surface that matches or substantially conforms to an anatomical surface (i.e., a cortical bone surface, a subchondral bone surface, a cartilage surface, an osteophyte, a bone void, a bone defect,

etc.) and at least a second surface matching or substantially conforming to (and/or resting against and/or abutting in some manner) one or more surfaces of the implant or implant components requiring revision (which may be a component to be revised, or a component that is not revised but which is adjacent to another component to be revised). If desired, the tools may also assist with the removal of the failed implant (i.e., locking onto the failed implant and incorporating a "slap hammer" connection, providing a cut plane for severing portions of the failed implant, sections of bone cement and/or interfering anatomical structures, etc.) or other alignment method to assist with removal of the "failed implant." In various embodiments, the surgical tool and/or mold will also provide an alignment guide or marker that can be utilized to place one or more (preferably two or more) alignment pins or wires which can provide one or more reference points for subsequent surgical steps (including the placement of subsequent surgical tools) after removal of the "failed implant" has been accomplished. Desirably, the tool will allow the alignment marker(s) to be placed, and then the tool (and failed implant) can be separated from the joint, leaving the alignment marker(s) undisturbed in their desired location(s) for use in further steps of the surgical procedure.

Once the failed implant has been removed (or while the failed implant is still attached to the joint, if the relevant anatomy is accessible), one or more surgical tools can be introduced along the designated alignment guides to prepare the joint for implantation of the revision implant. If desired, some preparation steps may be performed before removal of the failed implant, and some afterwards. In addition, it is contemplated that preparation of various anatomical surfaces will allow placement of subsequent alignment tools (using the newly prepared surface(s)) for guiding further surgical tools.

Once the underlying anatomical support structure has been prepared (and any augments deemed necessary have been positioned and/or secured to the support structure and/or to the implant surface(s), if necessary), the revision implant may be placed into the joint, and the surgery completed.

EXAMPLE 4

"Failed Implant" Assisted Hip Technique

Various embodiments of this disclosure can be used for facilitate treatment of a wide variety of joints, including revisions of hip joint implants. This disclosure can assist a surgeon in designing a revision implant for a failed hip joint, as well as be used to assist the surgeon in selecting pre-manufactured implants and/or modular implant components, including head and neck components for revision hip implants based on independent variables associated with physical characteristics of the implant, including leg length, offset, and anteversion. Desirably, the steps described herein can help a surgeon properly plan the revision surgery and reduce or eliminate a need to change a preoperatively-chosen implant or modular component (i.e., modular stem, neck or other feature of the implant).

Once a set of generated data (as previously described) is constructed using various image sources (including typical images for a hip replacement procedure which can be taken along two different directions, for example, anterior/posterior (NP) and lateral pelvic images may be taken of the hip joint) and appropriate image processing and evaluation steps, the information may utilized to design a patient-specific implant or implant components, and/or to select an implant and/or modular components. For example, the surgeon may desire a change in at least one of the variables, e.g., leg length, offset, and/or anteversion. The present method allows the surgeon to quickly and easily select a different modular neck based on an evaluation of one of the variables without requiring reevaluation of the other variables. The method can further include preoperative planning of the surgical procedure, which advantageously provides an intuitive system for the surgeon both preoperatively and during surgery.

A computer system with optional user input (including various criteria entered by a surgeon and/or implant designer/manufacturer) may be used to design/choose an appropriate revision implant based on anatomical constraints, or a dimensional template or other implant information may be used in conjunction with the generated image(s) to design/choose the implant and/or to preoperatively plan the surgical joint revision procedure. In various embodiments, the image of the "failed implant" may be subtracted, allowing the template to be utilized directly with the generated image. In other embodiments, the "failed implant" may remain on the image. If desired, the "failed implant" may be identified by a color code or shading that differentiates it from the remaining anatomy. Similarly, anatomical areas may be shaded, color coded or otherwise identified to reflect an anticipated "confidence" of the accuracy of the individual anatomical features of the generated image. For example, the estimated anatomical margins of the femoral canal may be shown on the image as "contour lines" or differing shapes or colors, corresponding to confidences of 100&, 99%, 95%, 90%, 85% and so on. A surgeon can use this information to design/choose an implant sized to fit within an anticipate confidence region or regions, as desired by the surgeon or user. In a similar manner, the use can utilize the contour lines to estimate the chances of each of a given set of implants to fit the anatomy of the generated image.

The dimensional template may be constructed of a piece of transparent plastic or other suitable material which may be overlaid on the image of the hip portion of the patient, or may be an electronic image or data set that is virtually overlaid or otherwise manipulated relative to the generated image data. The dimensional template/data set may include a plurality of reference points forming a grid coordinate system, for example, a Cartesian coordinate system, including a pattern of intersecting horizontal and vertical indicators or lines that provide coordinates for locating points. A plurality or system of dimensional templates may be provided corresponding to each available size or type of hip implant and/or implant component of a given hip implant system or systems.

Using generated image date of the patient's anatomical structure (optionally with the "failed implant components subtracted from the image), the data can be utilized to select appropriate implant components (and/or design an appropriate implant), which can include appropriate combinations of acetabular shells, liners (of varying materials, including plastics and polymers such as polyethylene, ceramics, metals or composites), femoral head size, diameter and shape, neck length, thickness, shape, length, size and angle (i.e., anteverted neck, a straight neck, or a retroverted neck) and femoral stem axis, length, thickness, width, shape, curvature, variation and/or angulation, or a single or multi-piece implant can be designed, selected and/or manufactured.

The femoral stem may be chosen in a conventional manner such that the representation of the stem on a dimensional template substantially fills the intramedullary canal of the femoral shaft of the generated image data, such that the actual femoral stem component of the hip implant will correctly fit the intramedullary canal of the actual femur. If desired, a non-uniform stem and/or non-cylindrical and/or other support/anchoring structure can be designed and/or selected

based upon the generated image data. Provision is thus made for cross-sections of the stem shaft to be rectangular or trapezoidal with pronounced longitudinal edges which can establish contact with the cortex to improve anchoring and long-term implant performance. Provision could also be made for an arcuate shape of the stem base body to be selected in particular with respect to curvature and length in relation to two oppositely disposed edges (i.e., a lateral edge and a medial edge) such that an end position or other portion of the stem base body has a plurality of contact positions to the cortex or other cortical bone within the femoral canal (i.e., three or more contact positions along the stem body). In this manner, the curvature of the base body and the length of the base body and/or of the shaft could be particularly matched pre-operatively to one another and the surrounding anatomy.

The various features of the revision implant need not necessarily match those of the primary implant, or even those of the original femur, femoral head or acetabular cup. For example, the revision femoral head location of center may not necessarily coincide with the original center of femoral head prior to revision surgery because the condition of the revision femoral head or other portions of the joint may dictate a different center for the head of the revision implant component. For example, if the original femoral head is severely deteriorated or is badly misshapen, the surgeon may desire a different center for the head of the revision implant than the current center for the original femoral head. Also, the surgeon may wish to correct some problem, e.g., laxity correction or bone alignment correction, which may cause the center for the head of the revision implant to be different than the center of femoral head. The pre-operative planning and evaluation phase permits the surgeon to obtain the preoperatively-planned values for the offset and the leg length for the modular or patient-designed components, including the neck component of the hip implant.

During various embodiments of the surgical planning phase, the surgeon (or implant/tool designer or automatic program) chooses a desired anteversion component from various planes of reference points and/or other image data. The representation of the femoral stem may be oriented relative to the image data to align with the intramedullary canal of the image of the femoral shaft. The surgeon may then use various planes of reference points to determine a desired anteversion component for the modular neck of the hip implant. In one exemplary procedure, the surgeon can determine the anteversion component first, and then determine the necessary leg length and offset values for the preoperative plan of the procedure. Additional planning steps can include deciding where the center of the head of the neck should be located and/or what anteversion component is necessary, as well as selecting/designing a neck corresponding to the assessed variables of leg length, offset, and anteversion. Desirably, the system will simplify the surgeon's ability to determine the optimal position of the center of the head of the neck **44**. In various embodiments, the system may utilize both NP and lateral views simultaneously, or may utilize a three-dimensional data image, with the chose/designed implants superimposed thereon to allow the surgeon/designer to simultaneously assess all three variables, i.e., anteversion, leg length, and offset.

Similar patient-specific and anatomy-specific designs can be selected/manufactured using the generated image data. For example, areas of particular weakness (i.e., thin bone sections or areas of limited cortical bone) can be accounted for in the design/selection of implant components. Alternatively, areas of greater strength and/or bone concentration (i.e., a thicker-than-expected pelvic bone capable of accommodating a larger than normal acetabular cup) can lead to differences in selection and/or design of the various implant components. In addition, unique anatomy (i.e., a pelvic bone that will require an acetabular cup of unusual or non-spherical outer surface characteristics) can be accounted for pre-operatively in the implant design. Similarly, surgical tools and jigs can be designed that match or otherwise conform to (1) anatomical structures only, (2) "failed implant" structures only and/or combinations thereof. These surgical tools can assist with alignment and placement of cutting/drill instruments to prepare the anatomical support structures (i.e., femur and/or pelvis) for implantation of revision implants. The tools/jigs can also be used to align and/or guide tools to assist in separating the failed implant components (i.e., failed acetabular cup and/or femoral stems or other components) and/or adhesive materials (i.e., bone cement and/or osteo-integrated surfaces) from the underlying anatomical support structures.

If desired, the surgical jigs and tools described herein (and the implants selected/designed as well) can be used to perform hemi-arthroplasty as well as facilitate total hip joint replacement. Such procedures could include the use of surgical tools and/or jigs that utilize alignment surfaces from only half of a joint (i.e., the femoral side of a hip joint) to align tools and implant components for use on the other side of the joint (i.e., the pelvis). Such alignment surfaces could match or otherwise substantially conform to anatomical and/or implant structures as previously described. In other embodiments, the surgical tools and/or jigs could utilize alignment surfaces from the same half of a joint as treated/implanted. In other alternative embodiments, the surgical tools and/or jigs could utilize alignment surfaces from both halves of the joint to align tools and implant components for use on one half and/or both sides of the joint.

Once the failed implant has been removed (or while the failed implant is still attached to the joint, if the relevant anatomy is accessible), one or more surgical tools can be introduced along the designated alignment guides to prepare the joint for implantation of the revision implant. If desired, some preparation steps may be performed before removal of the failed implant, and some afterwards. In addition, it is contemplated that preparation of various anatomical surfaces will allow placement of subsequent alignment tools (using the newly prepared surface(s) for guiding further surgical tools.

Once the underlying anatomical support structure has been prepared (and any augments deemed necessary have been positioned and/or secured to the support structure and/or to the implant surface(s), if necessary), the revision implant may be placed into the joint, and the surgery completed. If desired, the surgical procedure may involve replacement of only a single component or components, with other components remaining intact in the joint. For example, where an acetabular cup and/or femoral head has significantly degraded, but the femoral stem is well secured, the femoral stem may be allowed to remain in place, with the femoral head removed (if modular or otherwise removable in some manner) and replaced, and/or the acetabular cup replaced. Tools for use with such procedures could include jigs having combinations of patient-specific anatomic surfaces and/or implant-specific anatomical surfaces to assist in alignment and/or preparation of the underlying anatomical surfaces.

Aside from facilitating the creation/selection of implants particularized for a specific patient and/or surgical procedure and selecting/designing jigs for that procedure that utilize combinations of anatomy/implant features for alignment, the various embodiments described herein reduce and/or eliminate the need for a surgeon to trial or otherwise test the size and/or suitability of the implants and implant components in

the targeted joint. The use of patient-specific implants, in combination with tools that utilize patient and implant specific alignment surfaces, greatly reduces and/or eliminates the uncertainly associated with the implantation of joint implants, including revision implants.

Although described throughout with respect to a hip implant, the method could be utilized in any procedure which uses modular components, for example, but not limited to, shoulder implant procedures, knee implant procedures, etc.

EXAMPLE 5

"Failed Implant" Assisted Shoulder Technique

In a healthy shoulder, the proximal humerus is generally ball-shaped, and articulates within a socket formed by the scapula, called the glenoid, to form the shoulder joint. Conventional implant systems for the total replacement of the shoulder joint due to disease or trauma, i.e., a total shoulder arthroplasty, generally replicate the natural anatomy of the shoulder, and typically include a humeral component having a stem which fits within the humeral canal, and an articulating head which articulates within the socket of a glenoid component implanted within the glenoid of the scapula. An implant system for the replacement of only the humeral component of the shoulder joint, i.e., a hemi shoulder arthroplasty, typically includes only a humeral component which articulates within the natural glenoid socket of the scapula.

More recently, "reverse" type implant systems have been developed in which the conventional ball-and-socket configuration that replicates the natural anatomy of the shoulder is reversed, such that a concave recessed articulating component is provided at the proximal end of the humeral component that articulates against a convex portion of the glenoid component. Such reverse shoulder implant systems are thought to provide an increased range of motion for treatment of glenohumeral arthritis associated with irreparable rotator cuff damage, for example, by moving the center of rotation between the humeral component and the glenoid component to allow the deltoid muscles to exert a greater lever arm on the humerus.

Various embodiments of this disclosure are particularly well suited for treating and/or replacing failed or failing shoulder implants, as well as for converting "reverse" type implant systems to "normal" shoulder systems, and vica versa. By utilizing generated image data, the current condition of the failed/failing implant and the surrounding anatomical support structure can be determined with significant accuracy, and an appropriate revision implant (or implant components) can be selected and/or designed for the patient's needs. In addition, the creation of surgical tool and/or jigs that match or otherwise conform to (1) anatomical structures only, (2) "failed implant" structures only and/or any combinations thereof significantly facilitate the alignment and placement of cutting/drill instruments to prepare the anatomical support structures (i.e., glenoid and/or humerus) for implantation of revision implants. The tools/jigs can also be used to align and/or guide tools to assist in separating the failed implant components (i.e., failed glenoid cup or other components and/or humeral stems or other components) and/or adhesive materials (i.e., bone cement and/or osteo-integrated surfaces) from the underlying anatomical support structures.

In general, standard implant systems for total shoulder arthroplasties and hemi shoulder arthroplasties including a humeral stem having an enlarged head portion with interfaces adapted to removably receive various modular interchangeable components, such as articulating liners, spacers, and adapter inserts. The humeral stem typically functions as a universal platform that may be used in either conventional or "reverse" total shoulder arthroplasties, as well as hemi shoulder arthroplasties, and may remain implanted in place during a revision in which the implant system is converted between the foregoing configurations. Where failure of the implant is not attributable to failure of the humeral stem, it is desirable to retain the stem, as removal and replacement of the stem can often be a difficult procedure. An articulating liner on the stem generally articulates against a glenoid component, and may be angled to change the neck angle of the humeral stem from an angle suited for a conventional total arthroplasty or a hemi arthroplasty to an angle suited for a "reverse" total arthroplasty. The spacer may optionally be used to fit between the humeral stem and the articulating liner to provide increased joint tension when needed. An adapter insert can be used to provide an interface with a convex articulating component in a hemi arthroplasty application. A glenoid component is also typically provided that is mountable to the glenoid by a plurality of polyaxial locking screws or other devices or adhesives, and which receives a glenosphere having a smooth, convex and uninterrupted articulating surface against which the articulating liner of the humeral component may articulate.

In many occasions, failure of a primary shoulder joint implant occurs as a result of displacement or rotation of the glenoid component, especially where the anatomical supporting structures of the glenoid/scapula have further degraded since the initial surgery, if the initial glenoid component was oversized or otherwise suitable for the patient's anatomy, where the patient has failed to allow sufficient time for the components to integrate or secure to the underlying structure, and/or where trauma has occurred. Regardless of the underlying reason(s) for implant failure, however, the various embodiments of this disclosure can be used for facilitate treatment of a wide variety of joints, including revisions of shoulder joint implants. This disclosure can assist a surgeon in designing a revision implant for a failed shoulder joint, as well as be used to assist the surgeon in selecting pre-manufactured implants and/or modular implant components, including stem and cup components for revision shoulder implants. Desirably, the steps described herein can help a surgeon properly plan the revision surgery and reduce or eliminate a need to change a preoperatively-chosen implant or modular component.

Once a set of generated data (as previously described) is constructed using various image sources (including typical images for a shoulder replacement procedure which can be taken along different directions) and appropriate image processing and evaluation steps (including the use of prior patient images, if available), the information may utilized to design a patient-specific implant or implant components, and/or to select an implant and/or modular components. The present method allows the surgeon to quickly and easily select/design implant components based on an evaluation of many variables without requiring reevaluation of the other variables of the joint. The method can further include preoperative planning of the surgical procedure, which advantageously provides an intuitive system for the surgeon both preoperatively and during surgery.

A computer system with optional user input (including various criteria entered by a surgeon and/or implant designer/manufacturer) may be used to design/choose an appropriate revision implant based on anatomical constraints, or a template or other implant information may be used in conjunction with the generated image(s) to design/choose the implant and/or to preoperatively plan the surgical joint revision pro-

cedure. In various embodiments, the image of the "failed implant" may be subtracted, allowing the template to be utilized directly with the generated image. In other embodiments, the "failed implant" may remain on the image. If desired, the "failed implant" may be identified by a color code or shading that differentiates it from the remaining anatomy. Similarly, anatomical areas may be shaded, color coded or otherwise identified to reflect an anticipated "confidence" of the accuracy of the individual anatomical features of the generated image. For example, the estimated anatomical margins of the humeral canal or the margins of the glenoid bone may be shown on the image as "contour lines" or differing shapes or colors, corresponding to confidences of 100&, 99%, 95%, 90%, 85% and so on. A surgeon can use this information to design/choose an implant sized to fit within an anticipate confidence region or regions, as desired by the surgeon or user. In a similar manner, the use can utilize the contour lines to estimate the chances of each of a given set of implants to fit the anatomy of the generated image.

The template may be constructed of a piece of transparent plastic or other suitable material which may be overlaid on the image of the shoulder of the patient, or may be an electronic image or data set that is virtually overlaid or otherwise manipulated relative to the generated image data. The template/data set may include a plurality of reference points forming a grid coordinate system, for example, a Cartesian coordinate system, including a pattern of intersecting horizontal and vertical indicators or lines that provide coordinates for locating points. A plurality or system of templates may be provided corresponding to each available size or type of shoulder implant and/or implant component of a given shoulder implant system or systems.

Using generated image date of the patient's anatomical structure (optionally with the "failed implant components subtracted from the image), the data can be utilized to select appropriate implant components (and/or design an appropriate implant), which can include appropriate combinations of glenoid cups, humeral components (i.e., stems of differing length, thickness, shape, length, size and angle, heads of different size, diameter and shape, liners of varying materials, including plastics and polymers such as polyethylene, ceramics, metals or composites, etc.) and or sleeves or spacers, etc., or a single or multi-piece implant can be designed, selected and/or manufactured.

The various features of the revision implant need not necessarily match those of the primary implant. For example, the revision shoulder components could be a "reverse" shoulder, where the original failed should was a "standard" implant set. As another alternative, the revision glenoid cup may include one or more additional anchoring components, including a "glenoid or scapular stem" that extends from the glenoid fossa into the scapula. If desired, the generated image data can be utilized to design a glenoid cup component having an attached (or attachable) stem that follows a medullary canal of the scapula, which would permit replacement of a failed glenoid cup, even where significant damage to the glenoid bone obviates replacement with a standard cup.

As with other joint designs, the revision shoulder system need not be of the same design from the patient's original anatomy (although it could be designed the same, if desired), possibly because the condition of the revision humeral head or other portions of the joint may dictate a different center for the head of the revision implant component. For example, if the original humeral head is severely deteriorated or is badly misshapen, the surgeon may desire a different center for the head of the revision implant than the current center for the original humeral head. Also, the surgeon may wish to correct some problem, e.g., laxity correction or bone alignment correction, which may cause the center for the head of the revision implant to be different than the center of humeral head. The pre-operative planning and evaluation phase permits the surgeon to obtain the preoperatively-planned values for the offset and the leg length for the modular or patient-designed components, including the neck component of the shoulder implant.

In various embodiments, patient-specific and anatomy-specific designs for implants and/or tools can be selected/manufactured using the generated image data. For example, areas of particular weakness (i.e., thin bone sections or areas of limited cortical bone) can be accounted for in the design/selection of implant components. Alternatively, areas of greater strength and/or bone concentration (i.e., a thicker-than-expected scapular bone capable of accommodating a larger than normal glenoid cup) can lead to differences in selection and/or design of the various implant components. In addition, unique anatomy (i.e., a scapular bone that will require an glenoid cup of unusual or non-spherical outer surface characteristics, or one that requires additional support from a scapular stem) can be accounted for pre-operatively in the implant design. Similarly, surgical tools and jigs can be designed that match or otherwise conform to (1) anatomical structures only, (2) "failed implant" structures only and/or combinations thereof. These surgical tools can assist with alignment and placement of cutting/drill instruments to prepare the anatomical support structures (i.e., humerus and/or scapula/glenoid) for implantation of revision implants. The tools/jigs can also be used to align and/or guide tools to assist in separating the failed implant components (i.e., failed glenoid cup and/or humeral stems or other components) and/or adhesive materials (i.e., bone cement and/or osteo-integrated surfaces) from the underlying anatomical support structures.

If desired, the surgical jigs and tools described herein (and the implants selected/designed as well) can be used to perform hemi-arthroplasty as well as facilitate total shoulder joint replacement. Such procedures could include the use of surgical tools and/or jigs that utilize alignment surfaces from only half of a joint (i.e., the humeral side of a hip joint) to align tools and implant components for use on the other side of the joint (i.e., the scapula/glenoid). Such alignment surfaces could match or otherwise substantially conform to anatomical and/or implant structures as previously described. In other embodiments, the surgical tools and/or jigs could utilize alignment surfaces from the same half of a joint as treated/implanted. In other alternative embodiments, the surgical tools and/or jigs could utilize alignment surfaces from both halves of the joint to align tools and implant components for use on one half and/or both sides of the joint.

Once the failed implant has been removed (or while the failed implant is still attached to the joint, if the relevant anatomy is accessible), one or more surgical tools can be introduced along the designated alignment guides to prepare the joint for implantation of the revision implant. If desired, some preparation steps may be performed before removal of the failed implant, and some afterwards. In addition, it is contemplated that preparation of various anatomical surfaces will allow placement of subsequent alignment tools (using the newly prepared surface(s)) for guiding further surgical tools.

Once the underlying anatomical support structure has been prepared (and any augments deemed necessary have been positioned and/or secured to the support structure and/or to the implant surface(s), if necessary), the revision implant may be placed into the joint, and the surgery completed. If desired, the surgical procedure may involve replacement of only a single component or components, with other components

remaining intact in the joint. For example, where an glenoid cup and/or humeral head has significantly degraded, but the humeral stem is well secured, the humeral stem may be allowed to remain in place, with the humeral head removed (if modular or otherwise removable in some manner) and replaced, and/or the glenoid cup replaced. Tools for use with such procedures could include jigs having combinations of patient-specific anatomic surfaces and/or implant-specific anatomical surfaces to assist in alignment and/or preparation of the underlying anatomical surfaces.

Aside from facilitating the creation/selection of implants particularized for a specific patient and/or surgical procedure and selecting/designing jigs for that procedure that utilize combinations of anatomy/implant features for alignment, the various embodiments described herein reduce and/or eliminate the need for a surgeon to trial or otherwise test the size and/or suitability of the implants and implant components in the targeted joint. The use of patient-specific implants, in combination with tools that utilize patient and implant specific alignment surfaces, greatly reduces and/or eliminates the uncertainly associated with the implantation of joint implants, including revision implants.

EXAMPLE 6

Improvement to Standard Revision Procedure

The various embodiments of this disclosure disclosed herein can significantly reduce the complexity and/or significantly improve the outcome of a surgical procedure for revising a failed or failing joint implant. In the current practice, an example of which is described in the Zimmer Nexgen LOCK TKA Surgical Technique Guide (commercially available from Zimmer, Inc.), the access and immediate removal of a failed or failing joint implant is generally the initial step in a revision surgical procedure. Once implant removal has been accomplished, a surgeon is required to utilize a number of surgical tools and alignment guides, and generally prepare and implant one or more anchoring/measurement devices (i.e., intramedullary stems, etc.), in an initial effort to align and position various tools for guiding the subsequent surgical cuts and/or drill holes made into the anatomical support structure. In the case of preparing a tibia for a Nexgen revision implant, the surgeon is initially directed to remove the failed implant, and then must drill/ream into the tibial canal and place a provisional tibial stem or reamer within the canal. Numerous tools and/or alignment guides are then attached to the stem/reamer, including external alignment rods, cutting jigs and/or alignment/sizing plates, in an effort to create a desired anatomical support surface and choose the proper size/shape components to fit the created support surface. The Nexgen technique guide identifies over nine separate tools and attachments necessary to align and guide the cutting tools for preparing just the tibial surface and canal.

In contrast, various embodiments of this disclosure can accomplish the same alignment and surface preparation for the tibia utilizing a bare handful of tools. In one embodiment, an alignment jig can be created having an inner surface that matches and/or substantially conforms to some or all of the existing "failed implant" and/or the surrounding tibial bone surfaces (if desired). This jig can include a pair of openings on a lateral side to accommodate a plurality of alignment pins. The jig can further incorporate one or more slots or cutting guides, if desired, to facilitate the accurate and safe cutting of the tibial surface with the failed implant still in position in the joint (if desired). Alternatively, the jig can be removed after placement of the markers and/or the jig can "dock" with the failed implant and assist with implant removal. Once the jig and failed implant have been removed, a second jig (or the same jig initially used, but without any attached failed implant) can be positioned over the alignment pins, and drill guides and/or cutting slots on the jig can be accessed to prepare the tibial bone for the revision implant. Additional openings in the jig can accommodate additional surgical tools, if necessary, including saw blades for planar cuts as well as reamer and/or drill openings for placement of anchoring structures and/or support pins. The tibial surface is then prepared and ready for implantation.

The use of assessment and planning software, in combination with creation of jigs having anatomic-specific and//or implant-specific conforming features allows the surgery to be planned pre-operatively, allows the implant to be designed and/or selected to match the anticipated support structure for the revision implant, and allows the creation of jigs to be properly aligned without requiring the surgeon to resort to aligning the implant off an intramedullary canal or other anatomical features remote or unaffected by the joint implant failure or joint deterioration. In addition, the present embodiments significantly reduce the need for the surgeon to measure, evaluate and calculate alignment planes, cutting planes and reaming/drilling depths in a "free-hand" or "gut feel" manner, which can lead to significant mistakes and/or unintended consequences for the patient.

If desired, in addition to the tools and implants described herein, various additional embodiments contemplate the creation of a "backup" or "rescue" revision implant system and tools. It is possible, but highly unlikely, that the various embodiments described herein would recommend the creation of an implant and/or surgical tools that would not properly engage or substantially conform to the failed implant and/or the underlying anatomical structure of the failed joint. In such a case, a set of surgical tools can be created to accommodate a wide variety of variation in the implant surface and/or anatomical structure surface, yet provide sufficient alignment information to permit the surgical creation of a desired anatomical support structure and implantation of a replacement implant. In such cases, it may be desirable that the tools and/or implant include one or more "anatomical reliefs" to accommodate variations in the underlying structure(s). For example, a jig could be designed and constructed with a relative large internal cavity that accommodates a wide variety of implant shapes and sizes, but that includes one or more features that contact and/or otherwise interact with accessible known surfaces on the patient's bone and/or failed implant. Such features could include edges that conform to the outer cortical wall of the tibial tuberosity, and/or the tibal neck, with additional features that contact the upper surface of the failed tibial tray implant. Such a design could potentially accommodate a variety of tray perimeter sizes and/or thickness, while providing sufficient alignment and positioning information to prepare the tibial surface for implant placement. In various alternate embodiments, the tools and/or implant could incorporate one or more inserts that comprise a surface that matches or substantially conforms to an estimates anatomical or implant surface, but that can be removed (if desired) to reveal a different surface and/or anatomical relief surface for accommodating the unexpected anatomy/implant features.

EXAMPLE 7

Jigs for Creating Anatomical References

In various embodiments, the one or more jigs incorporating patient-specific and/or failed implant specific conforming

features desirably provide "known" reference point(s) and/or reference plane(s) for use by the surgeon during the surgical procedure. For example, the jigs may conform to and interact with reference features of the failed implant which are in a known relationship (through the image assessment and evaluation process) to one or more anatomical axis of the joint and/or limb. Placement of the jig onto the failed implant or some portion thereof, and subsequent placement of alignment markers through known jig alignment points (or relative to known alignment from the jib) and into the bone or relative to some other surface, allows the failed implant (and/or jig) to subsequently be removed while retaining known alignment position(s) relative to the joint. Subsequent tools can utilize the alignment markers in a known manner to align surgical cutting tools and create a desired anatomical support structure for the revision implant.

In a similar manner, other embodiments of jigs may utilize various combinations of failed implant surfaces and/or anatomical surfaces (or combinations thereof) to align jig components. Such tools could include implant only alignment, implant and anatomical structure alignment and/or anatomical structure only alignment. Such tools could also include various combinations of failed implant/anatomical alignment structures that also permit jig alignment using anatomy only, such as where the failed implant has been removed and/or alignment of the failed implant is uncertain (i.e., the implant shifts or rotates relatively freely or where it has been displaced or otherwise moved in an undesirable manner at some point during the surgical procedure).

Alternative embodiments of jigs may be utilized directly in contact with a failed implant, with the failed implant still attached and/or in position within the joint, and the jig could incorporate alignment guides that allow cutting or other preparation of the bone via unobstructed access around and/or through the failed implant. For example, one exemplary jig could include an inner surface that conforms in some manner to a failed tibial tray implant (additional alignment features could include the anterior cortex or other anatomical structures, including residual bone information as well as information on osteophytes and/or osteolysis). The jig could include a saw cut alignment guide adjacent to the anterior portion of the tibial head, yet positioned below the lower margin of the tibial tray (i.e., a set distance or height below the tibial plateau or other tibial surface). One or more cutting saws could be introduced through the alignment guide and cut portions of a planar tibial surface with the failed implant still in position. If desired, the alignment guide could incorporate "cut outs" or other such barriers (which may be modular and/or removable at the user's option) to prevent the saw blades from encountering undesirable obstructions or other anatomical areas, such as an intramedullary rod or tibial tray anchor extending down into the tibial bone from the failed tibial tray. Once sufficient surgical cutting has been accomplished, the jig may be removed, and then the implant may be removed (or they may be removed concurrently). Such steps may simplify the removal of failed implant components, and could significantly reduce the potential for additional anatomical damage caused when the implant and/or support structure (i.e., anchors, cement, bone ingrowth surfaces, etc.) is removed (possibly breaking additional anatomical structures off the bone).

EXAMPLE 8

Implants/Tools Accounting for Defects

Various embodiments of this disclosure contemplate the use of the generated image information to account for and/or accommodate defects and/or other undesirable anatomical features. For example, the generated image information can be utilized to determine areas of defects and/or osteolysis, as well as areas that may have degraded in some other fashion, or have anatomical structures that are desirably removed (i.e., osteophytes, etc.) prior to implantation of a revision prosthesis. If desired, the surgical tools and/or revision implant can be selected and/or designed to have "protrusions," voids or other such features that accommodate or otherwise fill or partially fill the defects and/or removed structures. Other embodiments can include the use of generated image information to select wedges, spacer blocks and/or other structures for use with the surgical tools and/or revision implant. These embodiments contemplate the use of surgical tools that account for the use of such structures, including the use of spacers or other structures that modularly "snap in" (or connect or secure to the tool on other such fashion) and may optionally be removable. Various modular pieces may include surfaces that conform to underlying anatomical or implant structures, such that they can be inserted and/or removed as needed during the surgical procedure to replicate the underlying surface(s) with which they interact.

EXAMPLE 9

Jigs to Prepare Femoral Canal

If desired, the various embodiments described herein can be utilized in conjunction with standard implants and/or surgical tools, including partial joint replacement/resurfacing systems and/or standard total joint (or partial joint) revision implant systems. As previously noted, the present systems can replace multiple tool sets used in standard systems to identify anatomical landmarks, guide cutting and drilling/reaming tools, and assist with removal of failed implant components as well as preparation of the anatomical support system for a replacement implant. If desired, various embodiments of this disclosure may also be used to assist with balancing of soft tissues and articulating surfaces.

One example of a jig to assist in preparation and/or placement of a standard revision implant system could include a patient-specific upper surface that substantially conforms to, or otherwise references, anatomical or other structures of the patient's femoral surfaces (i.e., anterior cortex, resected bone, bony defects, osteolysis, resected femoral surfaces and/or residual cement surfaces still integrated with the bone). An access or guide path is provided through the jig for a reamer, drill or other cutting instrument. Desirably, this guide path has been designed in conjunction with generated image data to follow a "desired trajectory" relative to an anatomical, mechanical or other axis determined from the image data. In various embodiments, the guide path is designed to avoid contact with the cortical wall of the canal, although other embodiments may seek such to abut or otherwise contact the cortical walls for potentially added anchoring strength or other objective. The guide path may be linear, cylindrical, tortuous, or any combination thereof.

A surgical cutting tool such as a drill or reamer may be introduced down the guide path and create a canal channel for accommodating a femoral stem or other anchoring device. The channel may be formed into virtually any shape, but will desirably be aligned by the guide path, and generally follow the contour of the channel. If desired, the channel may be curved or follow other shapes (i.e., may accommodate variations in the canal wall shape, etc.), with the stem or other

anchor designed in a similar shape to fit or otherwise be accommodated by the channel.

EXAMPLE 10

Optional Femoral Canal Tools

If desired, the surgical tool kit and implant system can include "optional" components or features that facilitate the surgeon's/implant's ability to accommodate unexpected anatomy and/or correct surgical "mistakes" or other undesirable events occurring during the surgical procedure. For example, the generated image data may indicate that sufficient natural anatomy remains (after removal of the failed implant) to support a revision implant without need for a femoral stem or other auxiliary support structure, but during the surgical procedure it becomes apparent that insufficient support structure remains. Similarly, anatomical support material that was intended to be used to support the revision implant may adhere to the failed implant and/or "break off" from the bone during implant removal or anatomical surface cutting and preparation.

In one embodiment a tibial jig could include an optional "plug" or other feature that, when removed, reveals a "guide path" formed in the jig to accommodate a tibial canal cutting tool (i.e., drill or reamer) for creating a channel within the tibial medullary canal for placement of a tibial stem or other auxiliary anchoring device. A tibial stem or other anchoring device could be included as part of the revision implant kit, to be utilized if necessary. In a similar fashion, the revision tibial tray could include optional connection devices (for securing to the tibial stem or other anchoring device), or an alternate tibial tray suitable for use with the anchoring device could be provided as well. If desired, blocks, wedges and/or other spacers may be provided as well.

Similar auxiliary anchoring devices could be provided for use with other joints or other joint portions, including the femoral side of the knee joint.

EXAMPLE 11

Implant Reference IJig® Surgical Tool for Revision Surgery

An Implant Reference Surgical Tool (e.g., an IJig® tool) can rest on an existing implant or implants, such as for example in a knee replacement, on the tibial plateau or femoral condyle in order to place a new, revision implant precisely on the tibial plateau or the femoral condyle.

In a conventional revision surgery, once the existing implant is removed, there is no clear useable references on the implantation site from which to generate a new, revision implant and related IJig® tools to place the new, revision implant.

In one aspect of this disclosure, original, electronically maintained files of the existing implant (e.g., an IUni® implant system) for a patient, if available, can be used as a reference for the placement of a new, revision implant (e.g., an IUni® implant system, IDuo® implant system, or ITotal® implant system). Further, to adjust for any placement issues during the original surgery, the electronic files can be compared to new image data obtained from the patient. Adjustments can be made to relocate the electronic implant such that it matches the location of the implant in accordance with the new image data. In one embodiment, the electronic files can be saved in a new location for making new reference files of the original implant that is now failing or otherwise in need of revision.

The original implant reference files (e.g., original electronic files used for making the original implant that is now failing and in need of revision) along with the patient's information (e.g., information about various surfaces of the patient's joint and/or the existing implant) from the new image data can now be used to determine the placement of a new implant. Accordingly, new surgical tools (e.g., IJig® tools) can be designed and made according to the desired placement of the new implant.

In certain embodiments, during the revision surgery, the existing implant in the patient will not be removed until at least one implant reference surgical tool have presented at least one cutting or drilling location.

The foregoing description of embodiments of this disclosure has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit this disclosure to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of this disclosure and its practical application, thereby enabling others skilled in the art to understand this disclosure and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of this disclosure be defined by the following claims equivalents thereof.

What is claimed is:

1. A method of making a surgical tool for use in implanting a revision implant for repairing a patient's joint, the method comprising:

obtaining image data associated with at least a portion of a failing joint implant;

deriving implant surface information and joint surface information from the image data; and

providing a surgical tool that includes a contact surface, the contact surface for engaging at least a portion of the failing implant surface and/or a surface portion of the patient's joint, the surgical tool further including at least one guide for directing movement of a surgical instrument in preparing a revision implant site, wherein providing the surgical tool includes:

shaping the contact surface based on the derived implant surface information such that at least a portion of the contact surface is substantially a negative of at least a portion of the derived implant surface and/or the derived surface portion of the joint; and

determining position, shape and/or orientation of the at least one guide from the image data, so that changes induced on the implant site by the surgical instrument ensures a desired orientation of a revision implant,

wherein the surgical tool is further configured to facilitate removal of the failing joint implant.

2. A method of performing a revision surgery for repairing a patient's joint that has a failing implant, comprising:

providing an implant reference surgical tool that includes a contact surface, the contact surface for engaging at least a surface portion of the failing implant and/or a surface potion of the patient's joint, wherein the contact surface is configured based on shape information about the surface portion of the failing implant and/or a surface potion of the patient's joint, and the surgical tool further includes at least one guide for directing movement of a surgical instrument in preparing a site for a revision implant;

engaging the contact surface of the surgical tool with the surface portion of failing implant and/or a surface potion of the patient's joint; and

preparing the revision implant site including removing the failing implant using the surgical instrument as directed by the at least one guide in the surgical tool.

3. The method of claim **2**, further including removing the failing implant.

4. The method of claim **2**, further including placing the revision implant on the prepared site.

5. The method of claim **2**, wherein the revision implant is configured based on information about the failing implant.

6. The method of claim **2**, wherein the revision implant is configured based on information about the patient's joint.

7. The method of claim **2**, wherein the contact surface is configured based on includes information about the patient's joint.

8. The method of claim **2**, wherein the surgical tool includes a surface portion that engages with a portion of the patient's joint, the surface portion is configured based on information about the portion of the patient's joint.

9. The method of claim **8**, wherein the surface portion substantially conforms to the portion of the patient's joint.

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